

# Exhibit 27

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF NEW YORK

3 IN RE: ACETAMINOPHEN - ) MDL No. 3043  
4 ASD-ADHD PRODUCTS )  
5 LIABILITY LITIGATION ) Case No.  
6 ) 1:22-md-03043-DLC  
7 THIS DOCUMENT RELATES TO: )  
8 ) JUDGE DENISE  
9 All Cases, 1:22-md-03043 ) COTE

10  
11 FRIDAY, SEPTEMBER 8, 2023

12 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

13 - - -

14 Videotaped deposition of Mary E.  
15 D'Alton, MD, held at the offices of Barnes &  
16 Thornburg, 390 Madison Avenue, 12th Floor,  
17 New York, New York, commencing at 8:53 a.m.  
18 Eastern, on the above date, before Carrie A.  
19 Campbell, Registered Diplomate Reporter,  
20 Certified Realtime Reporter, Illinois,  
21 California & Texas Certified Shorthand  
22 Reporter, Missouri, Kansas, Louisiana & New  
23 Jersey Certified Court Reporter.

24 - - -

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<p>6 ALSO PRESENT:  7 DANIEL OLIVO, Tracey Fox &amp; Walters,  8 (Via Zoom)  9 RAY MOORE, trial technician, Precision  10 Trial Solutions</p>	<p>21 930A 43rd Annual Pregnancy Meeting, 215  22 February 6-11, 2023, San  23 Francisco, California  24 936B "ACOG Response to Consensus 327  25 Statement on Paracetamol Use  26 During Pregnancy," September 29,  27 2021  28 937 "Fetal programming of mental 244  29 health by acetaminophen?"  30 Response to the SMFM statement:  31 Prenatal acetaminophen use and  32 ADHD," Olsen, et al.  33 938A "Prenatal acetaminophen use and 219  34 outcomes in children," SMFM  35 Statement  36 938B Society of Maternal-Fetal 210  37 Medicine 2017 Annual Report  38 962 "Epistemic Corruption, the 66  39 Pharmaceutical Industry, and the  40 Body of Medical Science,"  41 Sismondo  42 967 "Conflict of interest related to 112  43 clinical practice is  44 underreported: The case of  45 noninvasive prenatal testing,"  46 Wolfberg  47 968 Society of Maternal-Fetal 157  48 Medicine. The Pregnancy Meeting  49 38th Annual Meeting, January  50 30-February 3, 2019, Dallas, TX,  51 Hilton Anatole</p>
<p>11 VIDEOGRAPHER:  12 DANNY ORTEGA  13 Golkow Litigation Services  14 ---  15  16  17  18  19  20  21  22  23  24  25</p>	<p>21 930A 43rd Annual Pregnancy Meeting, 215  22 February 6-11, 2023, San  23 Francisco, California  24 936B "ACOG Response to Consensus 327  25 Statement on Paracetamol Use  26 During Pregnancy," September 29,  27 2021  28 937 "Fetal programming of mental 244  29 health by acetaminophen?"  30 Response to the SMFM statement:  31 Prenatal acetaminophen use and  32 ADHD," Olsen, et al.  33 938A "Prenatal acetaminophen use and 219  34 outcomes in children," SMFM  35 Statement  36 938B Society of Maternal-Fetal 210  37 Medicine 2017 Annual Report  38 962 "Epistemic Corruption, the 66  39 Pharmaceutical Industry, and the  40 Body of Medical Science,"  41 Sismondo  42 967 "Conflict of interest related to 112  43 clinical practice is  44 underreported: The case of  45 noninvasive prenatal testing,"  46 Wolfberg  47 968 Society of Maternal-Fetal 157  48 Medicine. The Pregnancy Meeting  49 38th Annual Meeting, January  50 30-February 3, 2019, Dallas, TX,  51 Hilton Anatole</p>

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1 VIDEOGRAPHER: We are now on  
 2 the record. My name is Danny Ortega,  
 3 and I'm the legal videographer for  
 4 Golkow Litigation Services.  
 5 Today's date is September 8,  
 6 2023, and the time is 8:53 a.m.  
 7 This video deposition is being  
 8 held at 390 Madison Avenue, New York,  
 9 New York, in the matter of  
 10 acetaminophen (Tylenol) ASD/ADHD  
 11 Products Liability Litigation.  
 12 The deponent is Mary D'Alton.  
 13 All counsel will be noted on  
 14 the stenographic record.  
 15 Our court reporter today is  
 16 Carrie Campbell and will now swear in  
 17 the witness.  
 18  
 19 MARY E. D'ALTON, MD,  
 20 of lawful age, having been first duly sworn  
 21 to tell the truth, the whole truth and  
 22 nothing but the truth, deposes and says on  
 23 behalf of the Plaintiffs, as follows:  
 24 /  
 25 /

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1 DIRECT EXAMINATION  
 2 QUESTIONS BY MR. TRACEY:  
 3 Q. Good morning, Dr. D'Alton.  
 4 A. Good morning.  
 5 Q. How are you?  
 6 A. I'm very well, thank you.  
 7 Q. Okay. My name is Sean Tracey.  
 8 I had hoped to meet you in person, and so  
 9 life got in the way so I appreciate everybody  
 10 accommodating me.  
 11 As I understand it, as I mark  
 12 exhibits during the day, somebody is going to  
 13 hand you -- I think Ray is going to hand you  
 14 hard copies so you can have a hard copy, if  
 15 that's okay.  
 16 Does that work?  
 17 A. That works perfectly. Thank  
 18 you.  
 19 Q. Okay. Yeah, I had hoped you  
 20 and I you could talk about our mutual Galway  
 21 connections in person, but maybe next time.  
 22 I saw, did you go to medical  
 23 school in Galway?  
 24 A. Yes, I did.  
 25 Q. And undergraduate -- well,

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1 actually, in Ireland, medical school is  
 2 undergraduate, isn't it?  
 3 A. Yeah. You go straight to  
 4 medical school from high school in Ireland.  
 5 Q. Okay. And where in Ireland are  
 6 you from?  
 7 A. I'm from Mayo, God Help Us, as  
 8 they say in Ireland.  
 9 Q. Yeah, where in Mayo?  
 10 A. I'm from a small town called  
 11 Killala. It's on the ocean there.  
 12 Q. Yeah, okay.  
 13 Well, my family is from  
 14 Glenamaddy, Galway. Some -- some cousins in  
 15 Mayo, but not many.  
 16 My uncle went to -- he went to  
 17 medical school at UCD.  
 18 So you -- as you understand it,  
 19 you work -- well, where do you work?  
 20 A. I work -- I'm employed by  
 21 Columbia University. I practice at New York  
 22 Presbyterian Hospital.  
 23 Q. And what do you do? What is  
 24 your title at Columbia University?  
 25 A. I'm chair of the department of

<p style="text-align: right;">Page 14</p> <p>1 obstetrics and gynecology at Columbia  2 University. Columbia University Medical  3 School.  4 Q. Okay. And how long have you  5 been the chair of the department of  6 obstetrics and gynecology at Columbia  7 University Medical School?  8 A. I've been chair there since  9 2003.  10 Q. And I know that you have given  11 many, many depositions; is that correct?  12 A. That's correct.  13 Q. I was able to dig up 26  14 different depositions of you over the years.  15 Do you have an idea of how many  16 you've actually given?  17 A. I have an idea. I don't  18 believe that it's totally accurate, but I  19 would say somewhere in the region between 70  20 and 80 depositions.  21 Q. Okay. And in those 70 or --  22 oh, have you testified live at trial?  23 A. Yes.  24 Q. How many times?  25 A. Trials are less frequent now.</p>	<p style="text-align: right;">Page 16</p> <p>1 for either a baby or her twins or triplets,  2 or the mom herself. And I'm asked to give an  3 opinion whether the standard of care was  4 adhered to and was appropriate by either  5 nurses or physicians or midwives, by health  6 care professionals. And if there was a  7 departure in the standard of care, whether  8 that departure contributed to the outcome.  9 Q. Okay. In those 30 trials, how  10 many of those trials did you testify on  11 behalf of the plaintiff?  12 A. Well, Mr. Tracey, I don't  13 usually testify on behalf of anybody. What I  14 do is I give my opinions in the case. But I  15 believe it was in three trials so far I've  16 been asked to give my opinions when attorneys  17 like yourself have been representing  18 plaintiffs.  19 Q. So 27 times you've been asked  20 to testify -- or you have testified and been  21 paid by defendants in the case?  22 A. By attorneys representing  23 defendants, yes. I have not been paid by  24 defendants, clearly.  25 Q. Okay.</p>
<p style="text-align: right;">Page 15</p> <p>1 I've probably testified in approximately 30.  2 MS. JOHNSTON: Hey, Sean, I'm  3 sorry to interrupt you. We've got a  4 bit of an echo. Can we take a  5 30-second break to fix that?  6 MR. TRACEY: Sure. Yeah. I'll  7 just mute.  8 VIDEOGRAPHER: The time right  9 now is 8:57 a.m. We're off the  10 record.  11 (Off the record at 8:57 a.m.)  12 VIDEOGRAPHER: The time right  13 now is 9:09 a.m. We are back on the  14 record.  15 QUESTIONS BY MR. TRACEY:  16 Q. Okay. Doctor, are you ready?  17 A. I'm ready.  18 Q. Okay. Before you had technical  19 difficulties, you were telling me you  20 testified about 30 times live at trial?  21 A. Yes.  22 Q. And in those 30 trials, what  23 types of cases were those generally?  24 A. Well, generally, I'm asked to  25 review cases where there's a untoward outcome</p>	<p style="text-align: right;">Page 17</p> <p>1 A. But also when I said 30, I  2 would say it's approximately 30. There might  3 be give or take. I -- I'm not 100 percent  4 sure.  5 Q. Yeah, no. Fair enough.  6 And then on the 70 or 80  7 depositions that you've given, how many of  8 those depositions were in cases where you  9 were hired by the plaintiffs?  10 A. Well, I don't actually know how  11 many because in the beginning, I was never  12 asked by -- when I started reviewing cases or  13 med mal cases, as we say, I was never asked  14 by plaintiffs representing patients. But  15 more recently, that number has increased.  16 And I would say a reasonable estimate of what  17 I do now is 15 to 20 percent of cases that I  18 review are when I'm asked by a plaintiff  19 attorney.  20 In terms of depositions, I  21 don't know. I'd say probably 15 depositions  22 or so I've done when I've been asked by  23 plaintiff attorneys to give my opinions.  24 Q. Okay.  25 A. Somewhere in that ballpark</p>

<p style="text-align: right;">Page 18</p> <p>1 would be a reasonable estimate.</p> <p>2 Q. Are you --</p> <p>3 A. I apologize, we talked over</p> <p>4 each other.</p> <p>5 I just followed up to say,</p> <p>6 somewhere in that ballpark of about 15 or so,</p> <p>7 give or take. There might be a bit more, I</p> <p>8 don't think there's that much less, would be</p> <p>9 a reasonable estimate.</p> <p>10 Q. Okay. Do you have any -- at</p> <p>11 the Columbia University, do you have -- other</p> <p>12 than being the chair of the OB/GYN</p> <p>13 department, do you have any responsibility</p> <p>14 for training residents or fellows?</p> <p>15 A. Well, I'm ultimately</p> <p>16 responsible because as chair of the</p> <p>17 department, you're responsible for the</p> <p>18 clinical care, the education and the</p> <p>19 research. So clearly I can't do all of that</p> <p>20 myself, but I'm responsible for putting the</p> <p>21 right people in charge of all of those areas.</p> <p>22 So I have a vice chair for</p> <p>23 education, a director for the residency</p> <p>24 program. We have a number of fellowships,</p> <p>25 and there are a number of fellowship</p>	<p style="text-align: right;">Page 20</p> <p>1 don't recall a specific instance.</p> <p>2 They may have, but I can't recall that</p> <p>3 for certain right now, so I honestly</p> <p>4 don't know.</p> <p>5 QUESTIONS BY MR. TRACEY:</p> <p>6 Q. Okay. Have you ever spoken to</p> <p>7 residents or fellows about whether or not</p> <p>8 acetaminophen can cause harm to a fetus?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: Quite honestly,</p> <p>12 as you know, I didn't know how to</p> <p>13 answer your previous question or I</p> <p>14 couldn't be sure about your previous</p> <p>15 question is, has a resident or a</p> <p>16 fellow ever asked me, then I'm not</p> <p>17 sure if I've ever spoken to a resident</p> <p>18 or a fellow.</p> <p>19 I certainly have not given</p> <p>20 lectures on it, but whether I have</p> <p>21 spoken about it or not, similar to my</p> <p>22 last answer, I can't be sure.</p> <p>23 QUESTIONS BY MR. TRACEY:</p> <p>24 Q. What about a patient? Have you</p> <p>25 spoken to a patient about whether or not</p>
<p style="text-align: right;">Page 19</p> <p>1 directors for each one of those.</p> <p>2 And then for research, I have a</p> <p>3 vice chair for research.</p> <p>4 So -- and then personally, I --</p> <p>5 I'm at rounds every week where I see the</p> <p>6 residents and fellows. When I see patients,</p> <p>7 I always have a fellow with me, who's</p> <p>8 assigned to me, who is training in</p> <p>9 maternal-fetal medicine.</p> <p>10 So I would say a large part of</p> <p>11 my -- of my responsibilities, and when I</p> <p>12 provide patient care, are with residents and</p> <p>13 fellows. And when I do rounds, there are</p> <p>14 residents and fellows with me. Maybe not at</p> <p>15 all times, but 99 percent of the times I have</p> <p>16 a resident or a fellow with me, and maybe a</p> <p>17 medical student.</p> <p>18 Q. And do these -- and do these</p> <p>19 residents or fellows ever ask you the</p> <p>20 question of whether or not Tylenol or</p> <p>21 acetaminophen can cause harm to a fetus?</p> <p>22 MS. JOHNSTON: Object to the</p> <p>23 form.</p> <p>24 THE WITNESS: I really don't</p> <p>25 know. I can't recall that. They -- I</p>	<p style="text-align: right;">Page 21</p> <p>1 acetaminophen has any risk to the fetus?</p> <p>2 MS. JOHNSTON: Object to the</p> <p>3 form.</p> <p>4 And, Sean, we're having some</p> <p>5 trouble with your video. You're</p> <p>6 breaking up quite a bit, so I think</p> <p>7 that's -- it -- it's causing some</p> <p>8 issues with your questions coming</p> <p>9 through clearly.</p> <p>10 MR. TRACEY: Great.</p> <p>11 Danny, is there anything you</p> <p>12 can do about that? I noticed the same</p> <p>13 thing.</p> <p>14 I've never had this issue</p> <p>15 before in my -- with Zoom, but -- so</p> <p>16 naturally it happened today. They're</p> <p>17 going -- is it any better now?</p> <p>18 MS. JOHNSTON: Not really,</p> <p>19 Sean. Do you want to -- we're still</p> <p>20 on the record. Do you want to go off?</p> <p>21 MR. TRACEY: Yeah, let's go off</p> <p>22 and see if we can fix it.</p> <p>23 MS. JOHNSTON: Okay.</p> <p>24 VIDEOGRAPHER: The time right</p> <p>25 now is 9:16 a.m. We are off the</p>

<p style="text-align: right;">Page 22</p> <p>1 record.</p> <p>2 (Off the record at 9:16 a.m.)</p> <p>3 VIDEOGRAPHER: The time right</p> <p>4 now is 9:18 a.m. We are back on the</p> <p>5 record.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Okay. Doctor, my last</p> <p>8 question, I think I'll repeat, because we had</p> <p>9 another technical issue.</p> <p>10 Have you ever spoken to</p> <p>11 patients about whether or not acetaminophen</p> <p>12 poses a risk to the fetus?</p> <p>13 MS. JOHNSTON: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: I've certainly</p> <p>16 been asked by patients, and I do this</p> <p>17 in my daily practice of reviewing a</p> <p>18 risk/benefit analysis of the use of</p> <p>19 acetaminophen, and what I recollect</p> <p>20 most often is that I was asked more</p> <p>21 frequently about this in the late</p> <p>22 fall, winter of 2021 and early 2022.</p> <p>23 QUESTIONS BY MR. TRACEY:</p> <p>24 Q. And what do you tell patients</p> <p>25 when they ask you about the risks of</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. Okay. So if a patient asked</p> <p>2 you whether the -- whether Tylenol poses a</p> <p>3 risk to the fetus, you just tell them no?</p> <p>4 MS. JOHNSTON: Object to the</p> <p>5 form.</p> <p>6 THE WITNESS: Well, I wouldn't</p> <p>7 say it quite that simply, Mr. Tracey,</p> <p>8 as I've tried to say this morning.</p> <p>9 My first question to them is,</p> <p>10 why do you want to take Tylenol.</p> <p>11 Let's talk about those reasons because</p> <p>12 it may very well be indicated in</p> <p>13 pregnancy for treatment of pain and</p> <p>14 fever.</p> <p>15 But what I would share with</p> <p>16 them is I always want to do an</p> <p>17 evaluation or would recommend that an</p> <p>18 evaluation be done prior to using</p> <p>19 drug -- a drug in pregnancy like</p> <p>20 acetaminophen.</p> <p>21 But I would share with them</p> <p>22 that all drugs have some risks, but</p> <p>23 that with respect to conditions for</p> <p>24 the fetus, I'm not -- from my review</p> <p>25 of the literature that I have done,</p>
<p style="text-align: right;">Page 23</p> <p>1 acetaminophen to the fetus?</p> <p>2 A. What I would say is, number</p> <p>3 one, acetaminophen should not be used without</p> <p>4 consultation with a health care provider. So</p> <p>5 I would recommend that you don't use it</p> <p>6 unless you talk to me about it so I can</p> <p>7 assess why you're taking it and what the</p> <p>8 potential underlying cause of either pain or</p> <p>9 fever would be. So that would be my first</p> <p>10 point.</p> <p>11 My second point --</p> <p>12 Q. All right.</p> <p>13 A. My second point is I personally</p> <p>14 will never tell you to take this unless I</p> <p>15 feel it's indicated and unless I have done an</p> <p>16 evaluation of why you are taking care of</p> <p>17 it -- why you want to take acetaminophen.</p> <p>18 And the third point I would say</p> <p>19 is, and what I have said to patients is, from</p> <p>20 my review of the available literature,</p> <p>21 there's no evidence of harm to a fetus with</p> <p>22 respect to ADHD or ASD, which is the dominant</p> <p>23 reason in late fall, early winter and 2022</p> <p>24 of -- of the time frame where I was asked by</p> <p>25 patients.</p>	<p style="text-align: right;">Page 25</p> <p>1 there's no causal link between ADHD</p> <p>2 and ASD.</p> <p>3 I would also be sure that they</p> <p>4 had an appropriate indication for it.</p> <p>5 And so those are all of the</p> <p>6 things that I'm thinking of in terms</p> <p>7 of when a patient asks me a question</p> <p>8 like that.</p> <p>9 QUESTIONS BY MR. TRACEY:</p> <p>10 Q. Okay. So, but I'm focusing now</p> <p>11 on the risks. The first two points were</p> <p>12 about benefit, and I asked -- my question was</p> <p>13 about risk to the fetus.</p> <p>14 And so I want to make sure that</p> <p>15 I understand what you tell patients when</p> <p>16 asked. And what you tell patients with</p> <p>17 respect to ASD and ADHD is that there is no</p> <p>18 risk to the fetus, right?</p> <p>19 A. That --</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: What I would say</p> <p>23 is what I have done is a review of the</p> <p>24 literature and that I cannot find from</p> <p>25 that review of the literature that</p>

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1 there's evidence of a causal link  
 2 between prenatal use of acetaminophen  
 3 and ADHD.  
 4 But in kind of a follow-up to  
 5 your question, when you're asked about  
 6 fetal risk, when you asked about fetal  
 7 risk, I would always want to tell a  
 8 patient there could be a risk of not  
 9 taking the drug to either herself or  
 10 her baby. Because one of the things  
 11 that I think about, as a person who  
 12 sees a lot of patients with high-risk  
 13 disorders, is that a fever or pain may  
 14 indicate a potential serious  
 15 underlying process for the mother.  
 16 So in terms of risk, I would  
 17 also talk to a patient about the risks  
 18 of not taking that drug.  
 19 QUESTIONS BY MR. TRACEY:  
 20 Q. Okay. Great. Thanks for  
 21 telling me that.  
 22 I'm actually, though, focused  
 23 on the risk of the drug right now. And I  
 24 just want, for clarity's sake, to make sure I  
 25 understand what you tell your patients right

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1 here, right now.  
 2 And right here, right now, your  
 3 testimony is that you tell patients who ask  
 4 you that there is -- you changed your answer  
 5 a little bit, which is why I'm asking again,  
 6 that there's no evidence of a causal link  
 7 between ASD and ADHD and acetaminophen.  
 8 Is that what you tell them now?  
 9 MS. JOHNSTON: Object to the  
 10 form.  
 11 THE WITNESS: What I tell them  
 12 now is that there is literature that  
 13 has been published but that my  
 14 analysis of that literature, and the  
 15 analysis that is done by our  
 16 professional societies, OB/GYN  
 17 societies and teratology societies  
 18 around the world, have not established  
 19 any causal link between AS -- prenatal  
 20 use of acetaminophen and ADHD and ASD.  
 21 QUESTIONS BY MR. TRACEY:  
 22 Q. Oh, okay. So you do discuss  
 23 with them and tell them that there's  
 24 literature that has been published that  
 25 raises the question of whether there's risk

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1 to the fetus with respect to acetaminophen  
 2 and ADHD and ASD?  
 3 MS. JOHNSTON: Object to the  
 4 form.  
 5 THE WITNESS: You asked me if  
 6 I'm asked directly about that, I do.  
 7 If I'm not asked directly, I don't.  
 8 QUESTIONS BY MR. TRACEY:  
 9 Q. Okay. I'm going to get to what  
 10 you do when nobody asks you in a second.  
 11 So right now I'm limiting my  
 12 question to when the question is raised by a  
 13 patient.  
 14 And so as I understand your  
 15 testimony, and correct me if I am wrong, if a  
 16 patient asks you the question, you will --  
 17 you will tell them there is literature that's  
 18 been published about a link between ADHD and  
 19 ASD and acetaminophen, but your review of the  
 20 literature, along with bodies that you  
 21 respect, is that there's no evidence of a  
 22 causal link; is that right?  
 23 MS. JOHNSTON: Object to the  
 24 form.  
 25 THE WITNESS: I'm not sure that

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1 I would say it like that.  
 2 What I would say is that  
 3 there's reported an association  
 4 between --  
 5 QUESTIONS BY MR. TRACEY:  
 6 Q. Okay.  
 7 A. -- ADHD and ASD. And my review  
 8 of that literature and all other obstetric  
 9 and gynecologic organizations around the  
 10 world that I know of, and the -- and the  
 11 teratology information services around the  
 12 world, have not -- have shown that there's no  
 13 clear causal link.  
 14 Q. No clear --  
 15 A. Causal link between prenatal  
 16 use of ADHD -- sorry, prenatal use, excuse  
 17 me, of acetaminophen and ADHD and ASD.  
 18 Q. So let me ask you this. When  
 19 you're -- when you're counseling women about  
 20 whether or not a drug may cause harm to the  
 21 fetus, do you require a clear causal link  
 22 before you caution them about taking drugs?  
 23 MS. JOHNSTON: Object to the  
 24 form.  
 25 THE WITNESS: It depends on

<p style="text-align: right;">Page 30</p> <p>1 what that information is what -- you</p> <p>2 know, there's a lot of drugs that we</p> <p>3 use in pregnancy.</p> <p>4 So you asked me -- your</p> <p>5 previous question was, what do I tell</p> <p>6 a patient if asked directly by a</p> <p>7 patient. So --</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. Yes, ma'am.</p> <p>10 A. -- it depends on what the</p> <p>11 underlying reason is for treatment of that</p> <p>12 underlying condition.</p> <p>13 Q. So if the under -- so if the</p> <p>14 underlying condition -- so if there are</p> <p>15 different indications for a drug, do you use</p> <p>16 different language with them or have a</p> <p>17 different standard with respect to whether or</p> <p>18 not a drug has been proven to have a causal</p> <p>19 link between the disease?</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: I mean, quite</p> <p>23 honestly, I have only done a causal</p> <p>24 link with respect to this drug because</p> <p>25 of the Bauer report that came out and</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Because you told me you didn't</p> <p>2 want to do that. You wanted to focus on</p> <p>3 fetal risk.</p> <p>4 Q. Well, no, no. But I'm going to</p> <p>5 do things methodologically here. I'm going</p> <p>6 to take things one step at a time.</p> <p>7 I'm happy to talk about</p> <p>8 risk/benefit, but right now, I'm focused on</p> <p>9 risk. We'll get to benefit. I assure you,</p> <p>10 we'll get to benefit. We'll talk about</p> <p>11 fever, and we'll talk about pain.</p> <p>12 Okay?</p> <p>13 A. Okay. Great. Thank you.</p> <p>14 Q. All right. But my question now</p> <p>15 was, do you only share risk information with</p> <p>16 your pregnant patients about drugs if there</p> <p>17 is a clear causal link between the drug and</p> <p>18 an outcome?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: I mean, it</p> <p>22 depends on what the drug is. That's</p> <p>23 a very, you know, broad question, and</p> <p>24 it depends on what the drug is, what</p> <p>25 the indication of it is, what -- how</p>
<p style="text-align: right;">Page 31</p> <p>1 the -- following that, the number of</p> <p>2 our organizations around the world who</p> <p>3 responded to that saying there is not</p> <p>4 a causal link.</p> <p>5 So I did that certainly in</p> <p>6 preparation for my report and in</p> <p>7 preparation for today.</p> <p>8 I certainly don't do a detailed</p> <p>9 causal link on every drug that I use</p> <p>10 in pregnancy, and it depends. It</p> <p>11 depends on the urgency. It depends on</p> <p>12 how familiar I am with the drug. It</p> <p>13 depends what the data is showing on</p> <p>14 that.</p> <p>15 So my objective always is to</p> <p>16 have a discussion with the patient</p> <p>17 about the risk/benefit analysis. And</p> <p>18 in thinking about risks and benefits,</p> <p>19 it's extremely important, although I</p> <p>20 know you don't want to talk about</p> <p>21 this, to think about the risks of not</p> <p>22 treating a pregnant patient.</p> <p>23 QUESTIONS BY MR. TRACEY:</p> <p>24 Q. Why do you think I don't want</p> <p>25 to talk about that, Dr. D'Alton?</p>	<p style="text-align: right;">Page 33</p> <p>1 familiar I am with using the drug. So</p> <p>2 I can't really answer that the way</p> <p>3 it's posed to me today.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. Okay. Well, you told me</p> <p>6 that that's what you do communicate to your</p> <p>7 patients that ask questions about</p> <p>8 acetaminophen. You tell them there's no</p> <p>9 clear causal link between ADHD and ASD,</p> <p>10 right?</p> <p>11 MS. JOHNSTON: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: When asked</p> <p>14 directly, as I've stated with --</p> <p>15 today, I would say to a patient that</p> <p>16 although associations have been</p> <p>17 reported in the literature, it is my</p> <p>18 own opinion, following a detailed</p> <p>19 review of the literature and the</p> <p>20 opinion of all of the obstetric</p> <p>21 societies around the world, or the</p> <p>22 vast majority of obstetric societies</p> <p>23 around the world, and the teratology</p> <p>24 societies here in Europe and in -- and</p> <p>25 in the US, that there is no causal</p>

<p style="text-align: right;">Page 34</p> <p>1 link; and similarly with the FDA.</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. Okay. And you think the FDA's</p> <p>4 position is there is no causal link between</p> <p>5 acetaminophen and ADHD and ASD?</p> <p>6 MS. JOHNSTON: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: FDA have</p> <p>9 recommended that there's no change in</p> <p>10 the current practice and that patients</p> <p>11 should consult with their health care</p> <p>12 provider prior to taking medication in</p> <p>13 pregnancy, as with all medicine.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. Okay. But that's different.</p> <p>16 Is it your position, do you</p> <p>17 believe the FDA believes as you've testified</p> <p>18 that there is no causal link between</p> <p>19 acetaminophen and ADHD and ASD?</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: Sorry, I'll have</p> <p>23 to look at their exact words, but it</p> <p>24 is something like that. I don't</p> <p>25 remember their specific words where</p>	<p style="text-align: right;">Page 36</p> <p>1 reviewed from the FDA is there is no</p> <p>2 clear evidence of a causal link</p> <p>3 between ADHD -- prenatal use of</p> <p>4 acetaminophen and ADHD and ASD.</p> <p>5 QUESTIONS BY MR. TRACEY:</p> <p>6 Q. Dr. D'Alton, have you had women</p> <p>7 who after speaking to you about this decide</p> <p>8 not to risk it, not to take Tylenol for</p> <p>9 whatever indication they may have been</p> <p>10 considering it for?</p> <p>11 MS. JOHNSTON: I object to the</p> <p>12 form.</p> <p>13 THE WITNESS: I don't know of</p> <p>14 any, but on the other hand, I'm not</p> <p>15 there in a patient's home or</p> <p>16 supervising whether they're taking</p> <p>17 their meds or not. So that's a very</p> <p>18 difficult question to answer</p> <p>19 specifically.</p> <p>20 On the other hand, I'm not</p> <p>21 aware of any patient that has</p> <p>22 certainly -- I don't know, but I'm not</p> <p>23 aware -- I'm not aware of it, if they</p> <p>24 haven't taken the drug for a specific</p> <p>25 indication.</p>
<p style="text-align: right;">Page 35</p> <p>1 they addressed this. But when I</p> <p>2 reviewed all of the FDA information</p> <p>3 that has been published on this from</p> <p>4 as early as 2015, I think, they have</p> <p>5 not -- they have stated that -- or</p> <p>6 some variation of this -- that the</p> <p>7 data so far had significant</p> <p>8 methodologic flaws and was not</p> <p>9 sufficient to support a causal link</p> <p>10 between acetaminophen and ADHD and</p> <p>11 ASD.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. Well, that's different than</p> <p>14 there's no causal link, isn't it?</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Well, I think not</p> <p>18 sufficient or no causal link is the</p> <p>19 same, in my opinion. There -- if</p> <p>20 you're going to make a recommendation</p> <p>21 or -- sorry, make a statement that</p> <p>22 there is a causal link or a potential</p> <p>23 causal link between ASD and ADHD, you</p> <p>24 better be very sure about it.</p> <p>25 And in my view and in what I've</p>	<p style="text-align: right;">Page 37</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Okay. But my question was, are</p> <p>3 you aware of any women who once you had this</p> <p>4 conversation with them about acetaminophen</p> <p>5 and ADHD and ASD, whether they decided not to</p> <p>6 risk it?</p> <p>7 MS. JOHNSTON: Object to the</p> <p>8 form.</p> <p>9 THE WITNESS: Well, I'm not</p> <p>10 aware of that, Mr. Tracey, at this</p> <p>11 point because you asked me -- this is</p> <p>12 when patients ask me about it, you --</p> <p>13 what I've shared with you today as</p> <p>14 best I recollect that patients asked</p> <p>15 me about this around the time frame of</p> <p>16 fall, winter 2021 and 2022.</p> <p>17 And I don't remember that any</p> <p>18 of those patients had an indication</p> <p>19 for use. They were just reacting to</p> <p>20 stories that were in the news.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. I see.</p> <p>23 A. So with respect to an</p> <p>24 indication, when there is an indication from</p> <p>25 patients, I am not aware of patients not</p>

<p style="text-align: right;">Page 38</p> <p>1 taking my advice or if that's the case,  2 they -- it's possible, but I'm not aware of  3 it.  4 Q. Yeah, fair enough. I  5 understand how it came up now.  6 (D'Alton Exhibit 999C marked  7 for identification.)  8 QUESTIONS BY MR. TRACEY:  9 Q. I'm going to bring up and  10 have -- hand you Exhibit 999C. It's a  11 portion of a transcript of Jennifer  12 Pinto-Martin.  13 Do you know who that is?  14 A. Yes, I do.  15 Q. Do you know Dr. Martin?  16 MS. JOHNSTON: One second,  17 Sean. We're getting the hard copy  18 now.  19 MR. TRACEY: Okay.  20 THE WITNESS: I don't know her  21 personally, no.  22 QUESTIONS BY MR. TRACEY:  23 Q. Have you read her report in  24 this case?  25 A. Yes, I did.</p>	<p style="text-align: right;">Page 40</p> <p>1 pretty -- pretty definitively answer  2 the question of whether acetaminophen  3 use in utero causes autism?"  4 Now, you know what an RCT is,  5 Doctor?  6 A. Yes, I do.  7 Q. And she answers:  8 "Well, it's a hypothetical  9 that's impossible to do, so I've never  10 really given it consideration. You  11 can't -- randomly assign women to  12 receive a medication at this point has  13 some suggestion of harm."  14 Mr. Snidow says:  15 "Right.  16 "Yeah, so that's kind of what I  17 was getting at. You think it would be  18 unethical, right?"  19 And then she goes on to say:  20 "We do not allow randomized  21 clinical trials, except at the moment  22 of what we call equipoise, where  23 there's not sufficient evidence on one  24 side or the other.  25 "It's very hard to establish</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Have you read her deposition?  2 A. No, I have not read her  3 deposition. I believe it was sometime this  4 week, and I was not provided that.  5 Q. Okay. Well, I'm going to show  6 you part of her deposition. You can go to  7 the next page.  8 She was asked a question -- you  9 understand she's an epidemiologist, right?  10 A. Yes, I do.  11 Q. Do you understand that she's  12 been hired by Johnson &amp; Johnson in this case?  13 MS. JOHNSTON: Object to the  14 form.  15 THE WITNESS: I knew that she  16 was one of the experts in this case  17 hired by the lawyers representing  18 Johnson &amp; Johnson, as I understand it.  19 QUESTIONS BY MR. TRACEY:  20 Q. Yes.  21 And we took her deposition a  22 few days ago, and she was asked a question by  23 my colleague, Mr. Snidow.  24 The question is:  25 "Do you think that an RCT would</p>	<p style="text-align: right;">Page 41</p> <p>1 that point in time, and I think we are  2 past that now because there are studies  3 suggesting a risk.  4 "And so, first of all, which --  5 what women would enroll in a study like  6 that? And it would be unethical."  7 Now, is this the first time  8 you're seeing Dr. Pinto-Martin's testimony?  9 A. Yes.  10 Q. Do you agree with  11 Dr. Pinto-Martin that we are past the point  12 of equipoise because there are studies  13 suggesting a risk?  14 MS. JOHNSTON: Object to the  15 form.  16 THE WITNESS: I don't agree  17 with Dr. Pinto-Martin. In my review  18 of the entire body of literature, from  19 the clinical perspective, is that  20 there's reporting of an association,  21 but that is not sufficient enough to  22 establish a causal link.  23 So there is --  24 QUESTIONS BY MR. TRACEY:  25 Q. Okay.</p>

<p style="text-align: right;">Page 42</p> <p>1 A. -- reported associations, but</p> <p>2 that is not sufficient to establish a causal</p> <p>3 link.</p> <p>4 Q. But you understand</p> <p>5 Dr. Pinto-Martin is an epidemiologist,</p> <p>6 correct?</p> <p>7 A. Yes, I understand we're very</p> <p>8 different.</p> <p>9 Q. You are, ma'am.</p> <p>10 And she -- did you know that</p> <p>11 she was a specialist in the epidemiology of</p> <p>12 autism?</p> <p>13 MS. JOHNSTON: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: I know that she's</p> <p>16 very highly qualified, and I don't</p> <p>17 remember all of her credentials, but I</p> <p>18 know that she's very highly qualified.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. And, Dr. D'Alton, you are not</p> <p>21 an epidemiologist?</p> <p>22 A. No, Mr. Tracey, I'm not an</p> <p>23 epidemiologist.</p> <p>24 Q. And do you know -- tell us what</p> <p>25 your -- what would your definition of an</p>	<p style="text-align: right;">Page 44</p> <p>1 disagree with the epidemiologist testifying</p> <p>2 on behalf of Johnson &amp; Johnson,</p> <p>3 Dr. Pinto-Martin?</p> <p>4 MS. JOHNSTON: Object to the</p> <p>5 form.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Is that right, Doctor?</p> <p>8 A. I don't disagree with some of</p> <p>9 these comments. I think there are studies</p> <p>10 that report a -- an association. I would not</p> <p>11 define it like that.</p> <p>12 Whether that's a disagreement</p> <p>13 or not, I really don't know.</p> <p>14 Q. Okay. The next sentence she</p> <p>15 says -- she asked the question:</p> <p>16 "What woman would enroll in a</p> <p>17 study like that?"</p> <p>18 Do you see that question?</p> <p>19 A. I do.</p> <p>20 Q. That seems like a really good</p> <p>21 question, doesn't it?</p> <p>22 MS. JOHNSTON: Object to the</p> <p>23 form.</p> <p>24 MR. TRACEY: I don't know why</p> <p>25 the screen is moving. Can you go down</p>
<p style="text-align: right;">Page 43</p> <p>1 epidemiologist be.</p> <p>2 MS. JOHNSTON: Object to the</p> <p>3 form.</p> <p>4 THE WITNESS: Well, an</p> <p>5 epidemiologist is somebody who looks</p> <p>6 at populations and looks at risk of</p> <p>7 disease in populations and works very</p> <p>8 closely usually -- or many times will</p> <p>9 work closely -- some will work very</p> <p>10 closely with clinicians. Other times</p> <p>11 they will not.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. Okay. And the science of</p> <p>14 epidemiology is the science that looks for</p> <p>15 causes of disease, right?</p> <p>16 MS. JOHNSTON: Object to the</p> <p>17 form.</p> <p>18 THE WITNESS: You know, I'm not</p> <p>19 an epidemiologist, so what the science</p> <p>20 is -- the objective of that science</p> <p>21 I -- I am not an epidemiologist, so I</p> <p>22 really wouldn't want to comment on</p> <p>23 that.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. Okay. In any event, you</p>	<p style="text-align: right;">Page 45</p> <p>1 to that question, please?</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. "What woman -- women would</p> <p>4 enroll in a study like that," that's the</p> <p>5 question, Dr. D'Alton.</p> <p>6 That is a good question of</p> <p>7 Dr. Pinto-Martin to ask, isn't it?</p> <p>8 MS. JOHNSTON: Object to the</p> <p>9 form.</p> <p>10 THE WITNESS: I really don't</p> <p>11 know whether it's a good or bad</p> <p>12 question to ask because I don't know</p> <p>13 what the design of the study would be</p> <p>14 and what the different arms of that</p> <p>15 study would be.</p> <p>16 So I would need to know more</p> <p>17 about it to make a determination of a</p> <p>18 hypothetical study.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. Well, she goes on to say "it</p> <p>21 would be unethical," doesn't she?</p> <p>22 MS. JOHNSTON: Object to the</p> <p>23 form.</p> <p>24 And, Sean, to the extent that</p> <p>25 you're going to continue to ask</p>

<p style="text-align: right;">Page 46</p> <p>1 questions about the two pages that</p> <p>2 you've shown the witness, I'd ask for</p> <p>3 a complete copy for her review.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. Okay. Can you answer my</p> <p>6 question, Doctor?</p> <p>7 A. That's what it states here. I</p> <p>8 would not be prepared to give a comment on</p> <p>9 that because I would not decide, based on a</p> <p>10 few paragraphs, whether it would be ethical</p> <p>11 or not ethical to conduct a randomized trial.</p> <p>12 What I would be much more</p> <p>13 concerned about is that we don't know of a</p> <p>14 safer alternative to acetaminophen for</p> <p>15 treatment of pain and fever in pregnancy as a</p> <p>16 clinician.</p> <p>17 Q. That's a different question,</p> <p>18 though.</p> <p>19 A. Well, it's -- it has to play</p> <p>20 into a randomized clinical trial about what</p> <p>21 you are going to do for treatment of pain and</p> <p>22 fever.</p> <p>23 So I would -- I would say it's</p> <p>24 kind of a different question, but in thinking</p> <p>25 about the ethics of a clinical trial in</p>	<p style="text-align: right;">Page 48</p> <p>1 of epidemiology at Indiana, and</p> <p>2 epidemiologists are involved with us</p> <p>3 in our -- in our design of clinical</p> <p>4 trials.</p> <p>5 So there is -- it's important</p> <p>6 to have the clinical and the</p> <p>7 epidemiologic input into a design of a</p> <p>8 clinical trial.</p> <p>9 MR. TRACEY: I'm going to</p> <p>10 object to nonresponsive.</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Doctor, do you know what</p> <p>13 informed consent is?</p> <p>14 A. Yes.</p> <p>15 Q. What is informed consent?</p> <p>16 A. It means different things</p> <p>17 depending on what it is. Sometimes it's a</p> <p>18 form where a patient will sign a form for</p> <p>19 conduct of -- for performance of a procedure,</p> <p>20 like surgery, for getting anesthesia.</p> <p>21 But for me, informed consent is</p> <p>22 a process more than a form. And it is the</p> <p>23 information that's given to a patient, given</p> <p>24 the circumstances of her health, her past</p> <p>25 medical history, her social history, the</p>
<p style="text-align: right;">Page 47</p> <p>1 obstetrics and gynecology, you would want to</p> <p>2 know what the randomization was and what it</p> <p>3 was -- how it would address what alternatives</p> <p>4 would be used to acetaminophen.</p> <p>5 Q. Doctor, you've never designed a</p> <p>6 randomized clinical trial, have you?</p> <p>7 MS. JOHNSTON: Object to the</p> <p>8 form.</p> <p>9 THE WITNESS: Well, actually,</p> <p>10 that's not true. I've been</p> <p>11 participating in designs of randomized</p> <p>12 clinical trial for my career.</p> <p>13 I was part of the randomized</p> <p>14 clinical trial in Canada and when I</p> <p>15 started off of using ritodrine for</p> <p>16 treatment of preterm labor. So I was</p> <p>17 very involved with the epidemiology</p> <p>18 group who were designing that study.</p> <p>19 And in many of the studies that</p> <p>20 I've participated in, whether they be</p> <p>21 randomized trials or whether they be</p> <p>22 clinical trials, we work with an</p> <p>23 epidemiologist.</p> <p>24 I have an epidemiologist in my</p> <p>25 department. He was formerly the chair</p>	<p style="text-align: right;">Page 49</p> <p>1 reason for the procedure or treatment in</p> <p>2 front of her and the benefits and risks of</p> <p>3 doing that.</p> <p>4 So --</p> <p>5 Q. Yeah --</p> <p>6 A. -- it is an information -- it's</p> <p>7 an information exchange between a provider</p> <p>8 and the patient about the risks and benefits</p> <p>9 of treatment.</p> <p>10 Q. Have you ever designed an</p> <p>11 informed consent form for patients to sign</p> <p>12 who were enrolling in clinical trials?</p> <p>13 A. Certainly I've been part of it</p> <p>14 because I was the PI for the largest study</p> <p>15 that has been done so far on screening for</p> <p>16 Down syndrome in pregnancy, and all of those</p> <p>17 patients required informed consent.</p> <p>18 I was also the principal</p> <p>19 investigator for fetal growth where it was a</p> <p>20 national study that was used to evaluate in</p> <p>21 patients who had no risk factors in pregnancy</p> <p>22 what was happening with fetal growth.</p> <p>23 So for all of our studies, we</p> <p>24 require a consent form and --</p> <p>25 Q. Do you remember my question,</p>

<p style="text-align: right;">Page 50</p> <p>1 Doctor?</p> <p>2 MS. JOHNSTON: Dr. D'Alton, if</p> <p>3 you want to finish your response, and</p> <p>4 then Mr. Tracey will ask you another</p> <p>5 question.</p> <p>6 THE WITNESS: I do remember</p> <p>7 your question, Mr. Tracey. You</p> <p>8 asked --</p> <p>9 QUESTIONS BY MR. TRACEY:</p> <p>10 Q. What was it?</p> <p>11 A. You asked me --</p> <p>12 Q. What was it?</p> <p>13 A. -- did I --</p> <p>14 MS. JOHNSTON: Sean, if you can</p> <p>15 please let Dr. D'Alton finish before</p> <p>16 you interrupt her.</p> <p>17 MR. TRACEY: Yeah, I'd just</p> <p>18 like her to answer my question.</p> <p>19 THE WITNESS: Okay. I believe</p> <p>20 you asked me what was your question,</p> <p>21 and your question was, did I ever do</p> <p>22 an informed consent -- did I ever</p> <p>23 design an informed consent for a</p> <p>24 clinical trial.</p> <p>25 And my answer was, although I</p>	<p style="text-align: right;">Page 52</p> <p>1 that.</p> <p>2 (Court Reporter read back</p> <p>3 question.)</p> <p>4 THE WITNESS: What I would say</p> <p>5 is that clearly the planning of a</p> <p>6 clinical trial like this would involve</p> <p>7 very significant input from a number</p> <p>8 of subspecialists, epidemiologists, if</p> <p>9 I was conducting a clinical trial,</p> <p>10 geneticists and OB/GYNs with</p> <p>11 information from patients.</p> <p>12 As I've stated before, I think</p> <p>13 it would -- in my opinion, it would</p> <p>14 require to tell patients about</p> <p>15 associations that have been reported.</p> <p>16 But I believe in that consent</p> <p>17 process, it would also be reasonable</p> <p>18 to say that no professional body that</p> <p>19 represents OB/GYN has determined a</p> <p>20 causal link at this point.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. So you would require the risks</p> <p>23 of ADHD and ASD to be disclosed to the</p> <p>24 mothers?</p> <p>25 MS. JOHNSTON: Object to the</p>
<p style="text-align: right;">Page 51</p> <p>1 may not have designed every aspect of</p> <p>2 it, I was involved in the informed</p> <p>3 consent design and process for the</p> <p>4 clinical trials that I've been</p> <p>5 involved in.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. All right. If you were going</p> <p>8 to design a clinical trial to study the</p> <p>9 effects of acetaminophen on fetuses, would --</p> <p>10 in your opinion, would you have to disclose</p> <p>11 to the mothers enrolling in this clinical</p> <p>12 trial the risk of ADHD and ASD, disclose that</p> <p>13 to them in writing, and get them to accept</p> <p>14 that risk?</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Sorry. Would --</p> <p>18 I lost the question, Mr. Tracey. I</p> <p>19 apologize. I lost my concentration</p> <p>20 for a minute.</p> <p>21 Would you -- could I have the</p> <p>22 question read back?</p> <p>23 MR. TRACEY: Yeah.</p> <p>24 THE WITNESS: Okay. Thank you.</p> <p>25 MR. TRACEY: Carrie can do</p>	<p style="text-align: right;">Page 53</p> <p>1 form.</p> <p>2 THE WITNESS: It's not exactly</p> <p>3 what I said. What I said was --</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. You did --</p> <p>6 A. First of all, I believe that I</p> <p>7 said reported association.</p> <p>8 Q. Okay. Okay. So you would have</p> <p>9 to disclose that to mothers in order to</p> <p>10 ethically enroll them in a clinical trial?</p> <p>11 MS. JOHNSTON: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: Well, quite</p> <p>14 honestly, Mr. Tracey, that's first off</p> <p>15 the top of my head about how I would</p> <p>16 design a clinical trial related to --</p> <p>17 a prospective trial related to</p> <p>18 acetaminophen.</p> <p>19 And that is something that I</p> <p>20 have not done and that I would want to</p> <p>21 think about with the input of many</p> <p>22 other investigators before I could</p> <p>23 really accurately answer your</p> <p>24 questions about the design of a</p> <p>25 potential trial. I would want to get</p>

<p style="text-align: right;">Page 54</p> <p>1 the information from many, many other</p> <p>2 subspecialists.</p> <p>3 Clearly, I would say that it is</p> <p>4 reasonable to tell a patient what is</p> <p>5 present in the literature, which in my</p> <p>6 estimation is that there is a reported</p> <p>7 risk that has been associated --</p> <p>8 reported association that has been</p> <p>9 associated.</p> <p>10 But there is no causal link</p> <p>11 that has been identified by ACOG,</p> <p>12 the -- and many other organizations</p> <p>13 around the world, as I've said, and</p> <p>14 the teratology societies around the</p> <p>15 world.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. Doctor, do you know what the</p> <p>18 logical fallacy of appeal to authority is?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: No, I have no</p> <p>22 idea what you're talking about,</p> <p>23 Mr. Tracey.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. Okay. You've never heard that</p>	<p style="text-align: right;">Page 56</p> <p>1 depends.</p> <p>2 I can't certainly blanket</p> <p>3 accept what every organization says,</p> <p>4 but in terms of whether I agree with</p> <p>5 it or not, I would do my own review.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Because organizations are made</p> <p>8 up of people, right?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. And people have biases, don't</p> <p>14 they, Doctor?</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Yes, people have</p> <p>18 biases.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. Some biases that people have</p> <p>21 are related to money, aren't they?</p> <p>22 MS. JOHNSTON: Object to the</p> <p>23 form.</p> <p>24 THE WITNESS: I would hope that</p> <p>25 a -- an organization is not producing</p>
<p style="text-align: right;">Page 55</p> <p>1 term, the appeal to an authority?</p> <p>2 MS. JOHNSTON: Same objection.</p> <p>3 THE WITNESS: If I've heard of</p> <p>4 it, I don't remember it. I've heard a</p> <p>5 lot of things because I've been around</p> <p>6 a long time, but whether I've ever</p> <p>7 heard about it, I can't tell you at</p> <p>8 this point.</p> <p>9 QUESTIONS BY MR. TRACEY:</p> <p>10 Q. Okay. I can assure you we're</p> <p>11 going to explore the ACOG and Society for</p> <p>12 Maternal-Fetal Medicine statements on</p> <p>13 acetaminophen at length and why and how it is</p> <p>14 they came to whatever conclusions they came</p> <p>15 to.</p> <p>16 But let me ask you this. Do</p> <p>17 you just accept at face value whatever</p> <p>18 organizations say, or do you look behind why</p> <p>19 they say what they say?</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: Number one, it</p> <p>23 depends on the issue at hand. If it's</p> <p>24 an issue that I'm exploring, I don't</p> <p>25 accept it at face value. So it</p>	<p style="text-align: right;">Page 57</p> <p>1 statements being influenced by money.</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. You would hope that, wouldn't</p> <p>4 you?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. Yes.</p> <p>10 Do you know who Dr. Andrea</p> <p>11 Baccarelli is?</p> <p>12 A. Yes, I do.</p> <p>13 Q. You mentioned that you work</p> <p>14 with epidemiologists at Columbia earlier.</p> <p>15 Do you know Dr. Baccarelli to</p> <p>16 be an epidemiologist at Columbia?</p> <p>17 A. I know that -- I don't exactly</p> <p>18 know all of his credentials, but I know that</p> <p>19 he's very well known for his work in the</p> <p>20 environment and in epigenetics.</p> <p>21 So -- and I have enlisted his</p> <p>22 help in recruiting a -- an environmental</p> <p>23 epidemiologist to my department, and she --</p> <p>24 we had a good collaboration around that, and</p> <p>25 she joined us last fall.</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. Okay. I just want Ray to put 2 up on the screen Dr. Baccarelli's picture. 3 And you recognize this as the 4 Columbia University website? 5 A. Yes. 6 Q. And this is the Mailman School 7 of Public Health at Columbia University? 8 A. Yes. 9 Q. That's one of the finest 10 schools of public health in the world, isn't 11 it? 12 A. I think it's something that 13 we're very proud of at Columbia, the Mailman 14 School of Public Health, yes. 15 Q. And Dr. Baccarelli is the chair 16 of the departmental -- Department of 17 Environmental Health Sciences and a professor 18 of epidemiology there, isn't he? 19 A. Yes. 20 Q. Now, if you scroll down a 21 little bit, Ray. 22 It says -- the last paragraph, 23 it says, "Dr. Baccarelli was elected to the 24 National Academy of Medicine for his 25 pioneering work showing that environmental</p>	<p style="text-align: right;">Page 60</p> <p>1 information on the environment and 2 obstetrics and gynecology. 3 QUESTIONS BY MR. TRACEY: 4 Q. Can you highlight that last 5 paragraph, Ray, or whoever has control of the 6 highlighting? 7 Did you know that he was cited 8 as being one of the most influential 9 scientists in the world for the past decade? 10 MS. JOHNSTON: Object to the 11 form. 12 THE WITNESS: No, I was not 13 aware of that. 14 QUESTIONS BY MR. TRACEY: 15 Q. Do you know Dr. Baccarelli to 16 be a scientist of impeccable integrity? 17 MS. JOHNSTON: Object to the 18 form. 19 THE WITNESS: Mr. Tracey, I 20 know of him. I don't know him 21 personally. I really can't comment on 22 his integrity because I don't know 23 him, and I know that he is an 24 established scientist with an 25 excellent reputation.</p>
<p style="text-align: right;">Page 59</p> <p>1 exposures adversely affect the human 2 epigenome and has been included in the Web of 3 Science list of highly cited, world's most 4 influential scientists of the past decade." 5 Did you know that? 6 MS. JOHNSTON: Object to the 7 form. 8 And, Sean, are you marking this 9 website as an exhibit? 10 MR. TRACEY: I wasn't going to, 11 no. 12 MS. JOHNSTON: Okay. 13 THE WITNESS: I knew that he 14 was elected to the Academy of Medicine 15 because I'm also in the Academy of 16 Medicine, so I usually know who's 17 appointed to the Academy of Medicine 18 on a yearly basis. 19 And I'm aware that he is very 20 well-known in his area of 21 environmental exposures, and that's 22 why I enlisted his help in recruiting 23 one of my epidemiologists in 24 environmental health to our department 25 because there is a dearth of</p>	<p style="text-align: right;">Page 61</p> <p>1 And as I stated, I've enlisted 2 him and his help in recruiting a 3 person that will have a joint 4 appointment in both of our 5 departments. 6 QUESTIONS BY MR. TRACEY: 7 Q. And have you read his report in 8 this case? 9 A. Yes, I have. 10 Q. Were you impressed with it? 11 MS. JOHNSTON: Object to the 12 form. 13 THE WITNESS: Well, I disagreed 14 with it, so I wasn't clearly impressed 15 with it. 16 QUESTIONS BY MR. TRACEY: 17 Q. Okay. Are you only impressed 18 by things you agree with? 19 MS. JOHNSTON: Object to the 20 form. 21 THE WITNESS: No, I'm impressed 22 by Dr. Baccarelli as a scientist in 23 the environment, but his report did 24 not impress me or change my opinion 25 that I've begun to state this morning.</p>

<p style="text-align: right;">Page 62</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Okay. Have you ever</p> <p>3 investigated Tylenol in autism or ADHD? Have</p> <p>4 you ever designed a study to look at that</p> <p>5 issue?</p> <p>6 A. Not at this point, no.</p> <p>7 Q. Do you have any plans to do it?</p> <p>8 A. Certainly I'm thinking about it</p> <p>9 because of the issues that have come up, but</p> <p>10 I have not made a determination on that point</p> <p>11 yet.</p> <p>12 Q. Would Dr. Baccarelli be the</p> <p>13 kind of epidemiologist you might consult to</p> <p>14 design a study?</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: No, I have not</p> <p>18 ever consulted Dr. Baccarelli in</p> <p>19 designing a study. I am fortunate</p> <p>20 that I have an epidemiologist in my</p> <p>21 own department. And as I've stated</p> <p>22 for you, I've already recruited</p> <p>23 another epidemiologist whose main</p> <p>24 interest is the environment.</p> <p>25 So we have an epidemiology</p>	<p style="text-align: right;">Page 64</p> <p>1 it down or do you have questions about</p> <p>2 Dr. Baccarelli's --</p> <p>3 MR. TRACEY: I have one more.</p> <p>4 MS. JOHNSTON: -- bio?</p> <p>5 QUESTIONS BY MR. TRACEY:</p> <p>6 Q. Do you know how you get to be</p> <p>7 on the list of highly cited, world's most</p> <p>8 influential scientists of the past decade?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Do you know how it works?</p> <p>13 A. No, I'm not familiar with the</p> <p>14 process for ranking scientists and their</p> <p>15 influence.</p> <p>16 Q. Okay. Do you know where</p> <p>17 Dr. Baccarelli ranks in his own area in terms</p> <p>18 of citations? How many times he's been cited</p> <p>19 by other researchers?</p> <p>20 A. No.</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: No, I do not.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. But you don't know where he</p>
<p style="text-align: right;">Page 63</p> <p>1 division in our department, so I would</p> <p>2 consult them rather than</p> <p>3 Dr. Baccarelli.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. Who is the epidemiologist that</p> <p>6 you hired that has a joint appointment in</p> <p>7 Dr. Baccarelli's department?</p> <p>8 A. I'm not sure if her joint</p> <p>9 appointment is through yet, but she -- her</p> <p>10 name is Blair Wiley.</p> <p>11 Q. Well -- I'm sorry, what was the</p> <p>12 first name?</p> <p>13 A. Blair, B-l-a-i-r.</p> <p>14 Q. Okay. And Dr. Baccarelli</p> <p>15 helped you find Dr. Wiley?</p> <p>16 A. Well, no. I found her, and I</p> <p>17 called him because she was interested in a --</p> <p>18 an appointment at the Mailman School in the</p> <p>19 environment, and he was absolutely delighted</p> <p>20 that she was thinking of joining me at</p> <p>21 Columbia and could think of a number of</p> <p>22 collaborative projects that would be done</p> <p>23 with his department and ours.</p> <p>24 MS. JOHNSTON: And hey, Sean,</p> <p>25 are you done with this? Can we pull</p>	<p style="text-align: right;">Page 65</p> <p>1 ranks in that regard among the scientists in</p> <p>2 the world?</p> <p>3 MS. JOHNSTON: Same objection.</p> <p>4 THE WITNESS: No, that is not</p> <p>5 something that I have looked into or</p> <p>6 evaluated.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. One of the measures of a</p> <p>9 scientist's influence is, though, however,</p> <p>10 how often other scientists cite their work,</p> <p>11 right?</p> <p>12 MS. JOHNSTON: Object to the</p> <p>13 form.</p> <p>14 THE WITNESS: That may be a</p> <p>15 measure, yes.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. Yeah.</p> <p>18 MR. TRACEY: Sarah, did you say</p> <p>19 you wanted a break?</p> <p>20 MS. JOHNSTON: I didn't, Sean,</p> <p>21 but it probably makes sense to -- I</p> <p>22 mean, I think we've been going about</p> <p>23 an hour.</p> <p>24 MR. TRACEY: Yeah, you wanted</p> <p>25 me to take this down.</p>

<p style="text-align: right;">Page 66</p> <p>1 MS. JOHNSTON: Yeah, I just</p> <p>2 asked if you were done with it because</p> <p>3 I think it's --</p> <p>4 MR. TRACEY: Yeah.</p> <p>5 MS. JOHNSTON: With the Zoom</p> <p>6 setup, I think it's a little</p> <p>7 distracting.</p> <p>8 MR. TRACEY: Yeah. No, let's</p> <p>9 take it down, and I'll go to -- I'll</p> <p>10 go to my next exhibit.</p> <p>11 (D'Alton Exhibit 962 marked for</p> <p>12 identification.)</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. Can you bring up 962, Ray, and</p> <p>15 please hand it to Dr. D'Alton?</p> <p>16 By the way, Dr. D'Alton, do you</p> <p>17 know what epistemic humility is?</p> <p>18 A. No.</p> <p>19 Q. Have you never heard the term</p> <p>20 before?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: I don't know if</p> <p>24 I've ever heard it or not, but</p> <p>25 certainly it's not something I'm</p>	<p style="text-align: right;">Page 68</p> <p>1 MS. JOHNSTON: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: I really can't</p> <p>4 comment. It's not something that I've</p> <p>5 thought about or that I'm aware of.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Well, let me ask you this.</p> <p>8 For decades, society has been</p> <p>9 concerned with pharmaceutical influence in</p> <p>10 medicine and science, have they not?</p> <p>11 MS. JOHNSTON: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: I don't know how</p> <p>14 long it's been going on, but I know</p> <p>15 that is a concern of the -- the</p> <p>16 conflict related to pharma -- the</p> <p>17 pharmaceutical industry and science.</p> <p>18 QUESTIONS BY MR. TRACEY:</p> <p>19 Q. All right.</p> <p>20 MS. JOHNSTON: Hey, Sean, Sean,</p> <p>21 before you ask your next question, it</p> <p>22 looks like we've only got one hard</p> <p>23 copy. I'm not sure if we have -- or</p> <p>24 is that -- is that it? Should -- are</p> <p>25 we missing some, or what's the --</p>
<p style="text-align: right;">Page 67</p> <p>1 familiar with.</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. Okay. What about epistemic</p> <p>4 corruption? Have you ever heard that term</p> <p>5 before?</p> <p>6 MS. JOHNSTON: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: You know, I've</p> <p>9 heard a lot, as I've said in previous</p> <p>10 things. It's very hard for me to tell</p> <p>11 you accurately whether I've heard</p> <p>12 something or not before because you</p> <p>13 hear a lot of things over the years</p> <p>14 you -- you've been alive. So I can't</p> <p>15 honestly tell you that.</p> <p>16 I have no recall for it.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. Okay. Do you know what</p> <p>19 epistemology is?</p> <p>20 A. No.</p> <p>21 Q. All right. Epistemology is the</p> <p>22 study of knowledge, how we come to know</p> <p>23 things.</p> <p>24 Does that -- does that make</p> <p>25 sense to you?</p>	<p style="text-align: right;">Page 69</p> <p>1 RAY MOORE: There's supposed to</p> <p>2 be two in the folders. Is there only</p> <p>3 one there?</p> <p>4 MS. JOHNSTON: Oh, it looks</p> <p>5 like -- okay. It looks like we've got</p> <p>6 another one. I don't think that we</p> <p>7 had --</p> <p>8 MR. TRACEY: Okay.</p> <p>9 MS. JOHNSTON: Okay. All</p> <p>10 right. We're good.</p> <p>11 MR. TRACEY: Yeah. And I</p> <p>12 should have said thank you for doing</p> <p>13 that. I'm going to mark as this as</p> <p>14 Exhibit 962. It should be marked to</p> <p>15 Dr. D'Alton's deposition.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. The name of this paper I want</p> <p>18 to talk to you about is called "Epistemic</p> <p>19 Corruption, the Pharmaceutical Industry, and</p> <p>20 the Body of Medical Science," by an author at</p> <p>21 the Department of Philosophy, Queen's</p> <p>22 University in Kingston.</p> <p>23 Are you familiar with it?</p> <p>24 A. I am familiar with it because I</p> <p>25 lived in Ottawa, Canada, for ten years. So</p>

<p style="text-align: right;">Page 70</p> <p>1 I'm familiar with the university -- Queen's 2 University in Kingston. 3 Q. It's a great university, isn't 4 it? 5 A. Queen's University itself 6 certainly has a high reputation in Canada. 7 Q. My grandfather went to medical 8 school there. 9 A. Great. So you have a -- 10 Q. Yeah. 11 A. -- you have a -- 12 MS. JOHNSTON: Wait for a 13 question. 14 THE WITNESS: Okay. 15 QUESTIONS BY MR. TRACEY: 16 Q. I have a bias, Doctor. That's 17 what I call it. 18 A. You like doctors. 19 Q. Yes. 20 Let's see what this author has 21 to say. He says, in the abstract, "When a 22 knowledge system importantly loses integrity, 23 ceasing to provide the kinds of trusted 24 knowledge expected of it, we can label this 25 epistemic corruption. Epistemic corruption</p>	<p style="text-align: right;">Page 72</p> <p>1 MS. JOHNSTON: Object to the 2 form. 3 THE WITNESS: I -- I'm not 4 aware of -- certainly in my own 5 work -- of influence from the 6 pharmaceutical companies affecting the 7 science that is done in my department. 8 I can only state about my 9 own -- my own experience at Columbia, 10 and where I would always want to have 11 complete editorial autonomy by our 12 investigators and no crossover between 13 the investigation that we do and the 14 pharmaceutical company. 15 QUESTIONS BY MR. TRACEY: 16 Q. Let me ask you this. Do you 17 take money from pharmaceutical companies in 18 your department? 19 MS. JOHNSTON: Object to the 20 form. 21 THE WITNESS: I have been 22 funded by pharmaceutical companies. I 23 have been funded by Merck for Mothers 24 here, which is a foundation for Merck 25 Pharmaceuticals to do work in New York</p>
<p style="text-align: right;">Page 71</p> <p>1 often occurs because the system has been 2 co-opted for interests at odds with some of 3 the central goals thought to lie behind it. 4 There is now abundant evidence that the 5 involvement of pharmaceutical companies 6 corrupts medical science." 7 Did I read that mostly correct? 8 MS. JOHNSTON: Object to the 9 form. 10 THE WITNESS: You read that 11 statement as it is reported here by 12 this author, yes. 13 QUESTIONS BY MR. TRACEY: 14 Q. Now, have you ever surveyed the 15 literature with respect to the evidence 16 showing that pharmaceutical involvement 17 corrupts medical science? 18 MS. JOHNSTON: Object to the 19 form. 20 THE WITNESS: Certainly I have 21 not searched the literature with 22 that -- to investigate that, no. 23 QUESTIONS BY MR. TRACEY: 24 Q. Do you know whether or not that 25 statement is true?</p>	<p style="text-align: right;">Page 73</p> <p>1 to reduce -- to see the effect -- 2 QUESTIONS BY MR. TRACEY: 3 Q. Dr. D'Alton -- Dr. D'Alton? 4 MS. JOHNSTON: I'm sorry, I'm 5 sorry. 6 MR. TRACEY: No, no, no. We're 7 not -- we're not going to add 8 filibustering. 9 QUESTIONS BY MR. TRACEY: 10 Q. My question is whether you 11 set -- 12 MS. JOHNSTON: Sean, she is 13 entitled to respond to your question. 14 MR. TRACEY: She's not entitled 15 to filibuster. That's wrong. 16 MS. JOHNSTON: Sean, she is 17 going to finish her response. 18 MR. TRACEY: No, no, I'm not 19 doing that. I have a limited amount 20 of time, and I'm not going to allow 21 speeches all day long. 22 MS. JOHNSTON: Dr. D'Alton, 23 were you finished with your response? 24 QUESTIONS BY MR. TRACEY: 25 Q. Here is my question,</p>

<p style="text-align: right;">Page 74</p> <p>1 Dr. D'Alton.</p> <p>2 MS. JOHNSTON: Sean, Sean,</p> <p>3 don't interrupt me either.</p> <p>4 Let her finish her response,</p> <p>5 then ask a new question.</p> <p>6 MR. TRACEY: No. No. I'm not</p> <p>7 playing that game.</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. Here's my question,</p> <p>10 Dr. D'Alton. Do you take money from</p> <p>11 pharmaceutical companies in your department?</p> <p>12 MS. JOHNSTON: Object to the</p> <p>13 form.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. And the answer to that is yes,</p> <p>16 isn't it?</p> <p>17 MS. JOHNSTON: Object to the</p> <p>18 form. Asked and answered.</p> <p>19 And, Sean, I'm looking at this,</p> <p>20 she was responding to your question.</p> <p>21 So this happens once. We're not doing</p> <p>22 it again.</p> <p>23 QUESTIONS BY MR. TRACEY:</p> <p>24 Q. Is the answer to the question,</p> <p>25 Dr. D'Alton, yes?</p>	<p style="text-align: right;">Page 76</p> <p>1 the middle of my previous response</p> <p>2 saying what it was for, but I don't</p> <p>3 believe you want to hear that.</p> <p>4 MS. JOHNSTON: No. Finish your</p> <p>5 response, Dr. D'Alton.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. What you did is you reasked my</p> <p>8 question because you didn't like it. So I'm</p> <p>9 going to try to clean it up, Doctor.</p> <p>10 Do you in your department</p> <p>11 accept funding from the pharmaceutical</p> <p>12 industry?</p> <p>13 MS. JOHNSTON: Object to the</p> <p>14 form. Asked and answered.</p> <p>15 THE WITNESS: We accept funding</p> <p>16 to conduct clinical trials by some</p> <p>17 pharmaceutical companies, yes.</p> <p>18 And our investigators have</p> <p>19 complete autonomy in those decisions.</p> <p>20 QUESTIONS BY MR. TRACEY:</p> <p>21 Q. I'm going to get to that issue,</p> <p>22 Doctor. Just be -- bear with me. We will</p> <p>23 get there.</p> <p>24 Okay?</p> <p>25 A. Thank you.</p>
<p style="text-align: right;">Page 75</p> <p>1 MS. JOHNSTON: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: Mr. Tracey, I</p> <p>4 don't like the way you asked me, do I</p> <p>5 take money.</p> <p>6 Our department is funded to</p> <p>7 conduct certain clinical trials. I</p> <p>8 don't take money from pharmaceutical</p> <p>9 trials -- pharmaceutical companies</p> <p>10 to --</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Okay. So let me -- let me ask</p> <p>13 it your way.</p> <p>14 MS. JOHNSTON: No. No. Sean,</p> <p>15 stop.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. Let me -- let me ask it your</p> <p>18 way.</p> <p>19 MS. JOHNSTON: Sean? No.</p> <p>20 Dr. D'Alton, please finish your</p> <p>21 response and let him ask you a new</p> <p>22 question.</p> <p>23 Are you finished with your</p> <p>24 response?</p> <p>25 THE WITNESS: Well, I was in</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. But I got to do this one step</p> <p>2 at a time.</p> <p>3 How long have you been</p> <p>4 accepting funding from the pharmaceutical</p> <p>5 industry to do your studies?</p> <p>6 MS. JOHNSTON: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: As best I can</p> <p>9 recollect, our funding for Merck for</p> <p>10 Mothers was in 2013 where we were</p> <p>11 funded to do studies all over New York</p> <p>12 State to reduce maternal mortality.</p> <p>13 I believe that funding ended in</p> <p>14 2016.</p> <p>15 We were additionally funded</p> <p>16 towards the end of the last decade to</p> <p>17 study a new device for treatment of</p> <p>18 postpartum hemorrhage, and that came</p> <p>19 from Alydia Health.</p> <p>20 And that was completed once we</p> <p>21 did a trial that was done at many</p> <p>22 different organizations around the</p> <p>23 country but lead by our investigators,</p> <p>24 and the trial was put forward by the</p> <p>25 investigators from Columbia and all</p>

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1 over the country.

2 QUESTIONS BY MR. TRACEY:

3 Q. Okay. Anything -- so that was,

4 you said, 2020?

5 A. I believe we published the

6 information either 2020 or 2021, but I

7 don't -- I can't be 100 percent specific on

8 that as -- at this point.

9 Q. Okay.

10 A. Without looking it up.

11 Q. And in this case, of course,

12 you're being paid, correct?

13 MS. JOHNSTON: Object to the

14 form.

15 THE WITNESS: Which case are we

16 talking about, sorry?

17 QUESTIONS BY MR. TRACEY:

18 Q. The case that you're testifying

19 in right now.

20 A. Okay. I apologize. I lost the

21 thread. You were asking me funding in our

22 department.

23 Yes, I'm being paid for my

24 time.

25 Q. Yeah, and that may have been my

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1 fault.

2 And as I understand it, it's

3 \$600 an hour?

4 A. Correct.

5 Q. And how many hours have you

6 billed in this case, Doctor, if you recall,

7 just generally?

8 A. I haven't billed anything so

9 far, Mr. Tracey.

10 Q. Oh. Good for them.

11 Do you know how many hours you

12 have accumulated?

13 A. I certainly know by the end of

14 July, there was 176 hours that I had spent

15 until that time.

16 Q. Okay. Okay. And that was at

17 the end of July?

18 A. Yes.

19 Q. Do you know how many hours you

20 have since then?

21 A. No. I haven't sat down to

22 calculate that yet.

23 Q. Okay. And is the money that

24 you get in this case, the one you're here

25 testifying in, does it go to you?

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1 A. Yes.

2 Q. Okay. All right. Back to the

3 article, "Epistemic Corruption, The

4 Pharmaceutical Industry, and the Body of

5 Medical Science."

6 We --

7 MS. JOHNSTON: And, Sean, I

8 don't want to interrupt you in the

9 middle of what you're going to do

10 here. I'm just going to flag that

11 we've been going for about an hour and

12 five.

13 So if we could take a break

14 once you're done with this line of

15 questioning.

16 MR. TRACEY: Yeah. No, that

17 would great. Good time for it.

18 QUESTIONS BY MR. TRACEY:

19 Q. If you flip over to the second

20 page, in the second paragraph there on the

21 left that starts with "my focus here," it

22 tells you what the author is doing.

23 It says, "My focus here is on

24 how the pharmaceutical industry corrupts

25 medical science. Using its very substantial

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1 resources, pharmaceutical companies co-opt

2 medical knowledge systems for their

3 particular interests, interests that conflict

4 with the integrity and at least some of the

5 central goals thought to lie behind medicine.

6 "It would seem that the body of

7 medical science is corrupted because some

8 assumed purity -- though purity is always

9 notionally -- has been affected by contact

10 with outside interests."

11 Do you see that, ma'am?

12 A. Yes, I do. That's highlighted

13 here, and that's how you read it.

14 Q. And that's certainly an

15 allegation that you've heard over the years,

16 correct?

17 MS. JOHNSTON: Object to the

18 form.

19 THE WITNESS: I mean, I can't

20 say I've heard every word like it is

21 here, but certainly I've heard

22 allegations of influence of the

23 pharmaceutical industry on science.

24 QUESTIONS BY MR. TRACEY:

25 Q. And if you go down two

<p style="text-align: right;">Page 82</p> <p>1 paragraphs, the one that starts with a 2017 2 Cochrane review. He puts a little meat on 3 the bone. 4 He says, "A 2017 Cochrane 5 review updated, from Lundh 2012, provides a 6 meta-analysis of such studies of industry 7 funding, in which 75 studies, comparing more 8 than 8,000 trials, met inclusion criteria. 9 "In all of its dimensions, the 10 2017 meta-analysis arrives at the same or 11 similar results as had earlier quantitative 12 and qualitative reviews. 13 "In the meta-analysis, industry 14 funding had a risk ratio of 1.27 of -- and of 15 producing favorable ethical -- of producing 16 favorable efficacy results, and of 1.34 of 17 drawing favorable overall conclusions." 18 And then you skip the next 19 sentence. It says, "Since there's no reason 20 to think that industry funding skews results 21 in any consistent direction, one can only 22 conclude that industry funding biases the 23 outcomes of clinical trials. 24 "Put simply, if a 25 pharmaceutical company funds a trial, the</p>	<p style="text-align: right;">Page 84</p> <p>1 a standard risk of bias factor in clinical 2 trials, one that is quantifiable, even 3 quantified, and pushes in predictable 4 directions. Industry funding affects the 5 results of clinical trials." 6 Ma'am, are you aware that some 7 researchers believe the mere fact of funding 8 is a bias -- a systematic bias in and of 9 itself? 10 MS. JOHNSTON: Object to the 11 form. 12 THE WITNESS: I don't believe 13 I've considered that before, 14 Mr. Tracey. And I can only comment on 15 my own -- on our department's 16 involvement with pharma -- 17 pharmaceuticals with respect to 18 clinical trials. 19 I'm not aware of this research, 20 and I would have to look it up. 21 QUESTIONS BY MR. TRACEY: 22 Q. Do you correct your own 23 pharmaceutical-funded studies for the bias 24 referenced here? 25 MS. JOHNSTON: I object to the</p>
<p style="text-align: right;">Page 83</p> <p>1 chances of results and conclusions in the 2 company favor are increased." 3 Have you heard those criticisms 4 before, ma'am? 5 MS. JOHNSTON: Object to the 6 form. 7 THE WITNESS: I have not heard 8 it in that kind of precision that you 9 have -- that you have recited here 10 this morning for me, so I have not 11 heard it like that. 12 QUESTIONS BY MR. TRACEY: 13 Q. And the next paragraph says, 14 "The authors of the Cochrane review conclude, 15 'Our analyses suggest the existence of an 16 industry bias that cannot be explained by 17 standard risk of bias assessments.' 18 "When pharmaceutical and other 19 companies sponsor research, there is a bias, 20 a systematic tendency towards results serving 21 their interests, but the bias is not seen in 22 the formal factors routinely associated with 23 low-quality science. 24 "The implication is the 25 industry funding itself should be considered</p>	<p style="text-align: right;">Page 85</p> <p>1 form. 2 THE WITNESS: Well, what I 3 would tell you is -- Mr. Tracey, is 4 what I said in my previous answer, is 5 that our investigators have complete 6 editorial separation from 7 pharmaceutical -- from the 8 pharmaceutical industry when we get 9 funding from this, like we did in the 10 two examples I gave you where I was 11 personally involved. 12 So I am confident that the -- 13 there was no evidence of bias in what 14 we found in the studies that were 15 funded by Merck for Mothers and 16 Alydia Health. 17 QUESTIONS BY MR. TRACEY: 18 Q. But, Dr. D'Alton, you 19 understand what these researchers are saying 20 is, even though you don't think there was any 21 bias, the mere fact of funding across 8,000 22 studies proved otherwise? 23 MS. JOHNSTON: Object to the 24 form. 25 THE WITNESS: You know, it's</p>

<p style="text-align: right;">Page 86</p> <p>1 not my experience, Mr. Tracey, as I've</p> <p>2 said to you. I would have to look at</p> <p>3 these studies to make a comment on it,</p> <p>4 and this is -- you know, this is</p> <p>5 something that I have not reviewed</p> <p>6 before today.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. Okay. The next paragraph says,</p> <p>9 "But funding is rarely just funding."</p> <p>10 They say, "The Cochrane Review</p> <p>11 I have just described shows that the</p> <p>12 pharmaceutical industry corruption of medical</p> <p>13 science doesn't happen through the mechanisms</p> <p>14 currently assessed by typical, formal</p> <p>15 methodological measures. Funding itself</p> <p>16 corrupts medical science, but this does not</p> <p>17 mean that it's mysterious."</p> <p>18 In the next paragraph he says,</p> <p>19 "There is abundant evidence that conflicts of</p> <p>20 interest are important in many domains,</p> <p>21 including across medicine. For example,</p> <p>22 financial conflicts on committees producing</p> <p>23 clinical practice guidelines tend to produce</p> <p>24 assessments of evidence and recommendations</p> <p>25 that favor the companies and industries</p>	<p style="text-align: right;">Page 88</p> <p>1 clinical practice guidelines tend to produce</p> <p>2 assessments of evidence and recommendations</p> <p>3 that favor the companies and industry</p> <p>4 involved."</p> <p>5 Are you familiar with the</p> <p>6 literature that's being cited there?</p> <p>7 MS. JOHNSTON: Object to the</p> <p>8 form.</p> <p>9 THE WITNESS: No, I am not</p> <p>10 familiar with this particular</p> <p>11 literature from 2013 and 2020. I</p> <p>12 would have to look it up.</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. Okay. Do you belong to the</p> <p>15 Society for Maternal-Fetal Medicine? You do,</p> <p>16 don't you?</p> <p>17 A. Yes, I do.</p> <p>18 Q. And you belong to ACOG, do you</p> <p>19 not?</p> <p>20 A. Yes. I'm a member -- a fellow</p> <p>21 of the American College of Obstetricians and</p> <p>22 Gynecologists.</p> <p>23 Q. Okay.</p> <p>24 MS. JOHNSTON: Sean, and I want</p> <p>25 to --</p>
<p style="text-align: right;">Page 87</p> <p>1 involved," and then he cites Cosgrove and</p> <p>2 Lexchin.</p> <p>3 Are you familiar with those</p> <p>4 studies?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: No, I am not</p> <p>8 familiar with those studies.</p> <p>9 (Audio interruption.)</p> <p>10 MR. TRACEY: Did I lose -- are</p> <p>11 you guys there?</p> <p>12 MS. JOHNSTON: Yeah, Sean, I</p> <p>13 think someone on the Zoom is not muted</p> <p>14 or there's some sort of issue with</p> <p>15 somebody who just joined the Zoom.</p> <p>16 MR. TRACEY: Yeah, yeah. Okay.</p> <p>17 I think it was a gremlin in my</p> <p>18 computer.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. So let me reask the question,</p> <p>21 Doctor. That sentence where they say -- it's</p> <p>22 highlighted, "There's abundant evidence that</p> <p>23 conflicts of interest are important in many</p> <p>24 domains across medicine. For example,</p> <p>25 financial conflicts on committees producing</p>	<p style="text-align: right;">Page 89</p> <p>1 MR. TRACEY: Yeah. Yeah.</p> <p>2 Let's --</p> <p>3 MS. JOHNSTON: If you're done</p> <p>4 with this one, can we take a break?</p> <p>5 MR. TRACEY: Yeah, let's take a</p> <p>6 break.</p> <p>7 MS. JOHNSTON: Great.</p> <p>8 MR. TRACEY: Five minutes?</p> <p>9 MS. JOHNSTON: Yeah, that's</p> <p>10 fine.</p> <p>11 VIDEOGRAPHER: The time right</p> <p>12 now is 10:20 a.m. We are off the</p> <p>13 record.</p> <p>14 (Off the record at 10:20 a.m.)</p> <p>15 VIDEOGRAPHER: The time right</p> <p>16 now is 10:38 a.m. We're back on the</p> <p>17 record.</p> <p>18 (D'Alton Exhibit 921 marked for</p> <p>19 identification.)</p> <p>20 QUESTIONS BY MR. TRACEY:</p> <p>21 Q. I'm going to hand you an</p> <p>22 article that you actually wrote. It's</p> <p>23 Exhibit 921. It's called "Scientific</p> <p>24 Evidence Underlying the American College of</p> <p>25 Obstetricians and Gynecologists' Practice</p>

<p style="text-align: right;">Page 90</p> <p>1 Bulletins." And it says it's original 2 research. 3 Do you remember this article? 4 MS. JOHNSTON: One second, 5 Sean. We're just getting a copy. 6 Sorry. 7 MR. TRACEY: Oh. Yeah, sorry. 8 MS. JOHNSTON: 921? 9 MR. TRACEY: Yeah, this is 921. 10 QUESTIONS BY MR. TRACEY: 11 Q. And do you see your name there, 12 Dr. D'Alton, Mary E. D'Alton there? 13 A. Yes, I do. 14 Q. And that's you, right? 15 A. Yes. 16 Q. And this is a study that you 17 wrote with other authors or that you 18 conducted with other authors to explore the 19 quality of evidence that underline ACOG 20 practice bulletins, right? 21 A. Let me just look. If you just 22 give me a minute to look at it and refresh my 23 memory. 24 Q. I think the answer is contained 25 in the title.</p>	<p style="text-align: right;">Page 92</p> <p>1 THE WITNESS: Yes. ACOG wrote 2 a response to the Bauer '21 document, 3 yes. 4 QUESTIONS BY MR. TRACEY: 5 Q. Yes, Doctor. We're going to 6 get to that shortly. 7 You go on to say, "Few studies 8 have examined the quality of scientific data 9 underlying evidence-based guidelines. We 10 examined the quality of evidence that 11 underlies the recommendations made by the 12 American College of Obstetricians and 13 Gynecologists, the College." 14 That's -- sometimes you guys 15 call it "the College," right? 16 A. Correct. 17 Q. Down at the bottom, you'll just 18 see you published this in 2011 or it was 19 published by ACOG in 2011. 20 Do you see that? 21 A. Yes, it was published by 22 The Green Journal, which is the major journal 23 of ACOG. 24 Q. Yes. 25 Then it's got -- down there</p>
<p style="text-align: right;">Page 91</p> <p>1 A. Yes, I've just had an 2 opportunity to take a look at it. Thank you. 3 Q. Okay. And let's look at the 4 objective. 5 This is -- this is your study, 6 right? 7 A. Well, I'm part of this study. 8 The lead author is Jason Wright. 9 Q. Yeah, sure enough. 10 But you're -- you signed the 11 study. You're one of the authors? 12 A. That is correct. 13 Q. It says the "Objective." It 14 says, "Clinical guidelines are an important 15 source of guidance for clinicians." 16 And that, of course, is true, 17 isn't it? 18 A. Yes. 19 Q. For example, ACOG has a 20 response to the consensus statement with 21 respect to whether or not guidelines for 22 dispensing Tylenol during pregnancy should be 23 changed, right? 24 MS. JOHNSTON: Object to the 25 form.</p>	<p style="text-align: right;">Page 93</p> <p>1 it's got "From the Divisions of Gynecologic 2 Oncology and Maternal-Fetal Medicine, 3 Department of Obstetrics and Gynecology, 4 Columbia University" there, right? 5 That's where the authors were? 6 A. That is correct. 7 Q. If we go over to the 8 paragraph -- the second full paragraph on the 9 right, it says, "The past two decades have 10 witnessed a dramatic increase in the number 11 of available guidelines. For adult 12 pharyngitis alone, there are ten different 13 guidelines from various groups. 14 "Although guidelines provide 15 useful information for clinicians, they have 16 limitations. First and foremost, guidelines 17 are only as good as the evidence that 18 underlies them. Evaluations of a number of 19 guidelines have found that many 20 recommendations are based on low-quality 21 evidence and expert opinion. 22 "This is particularly 23 problematic as expert opinion is subject to 24 bias, either implicit -- implicit or 25 subconscious."</p>

<p>Page 94</p> <p>1 Did I read all that correctly, 2 Doctor?</p> <p>3 A. Yes, you did. You've read that 4 correctly.</p> <p>5 Q. And when you-all said this, you 6 had concerns about the quality of the ACOG 7 guidelines, didn't you?</p> <p>8 MS. JOHNSTON: Object to the 9 form.</p> <p>10 THE WITNESS: I'm not sure that 11 we had concerns about the quality of 12 the ACOG guidelines. We wanted to 13 review the ACOG guidelines to see what 14 level of evidence was in the ones that 15 we studied in the 84 practice 16 bulletins that we studied to determine 17 the quality of the evidence behind 18 each one.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. Yes. Yes, Doctor. 21 And the lowest kind of 22 evidence, the lowest quality evidence you 23 write is of expert opinion?</p> <p>24 A. Sorry, where is that? I 25 apologize.</p>	<p>Page 96</p> <p>1 implicit or subconscious, what that means is 2 that whoever is writing the bulletins may 3 have biases that we don't know about, and 4 those biases could even be subconscious; that 5 is, the author doesn't even recognize the 6 bias, right?</p> <p>7 MS. JOHNSTON: Object to the 8 form.</p> <p>9 THE WITNESS: That's possible.</p> <p>10 QUESTIONS BY MR. TRACEY:</p> <p>11 Q. Yeah. 12 In fact, you cited to four 13 articles to prove that point, didn't you? 2, 14 4, 11 and 12.</p> <p>15 MS. JOHNSTON: Object to the 16 form.</p> <p>17 THE WITNESS: Let me just look 18 at that.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. Do you want to look at them? 21 We'll look at them one by one, if you want. 22 If you'll turn, Ray, to the 23 references for the claim they made there. 24 Number 2 is a article called "Why 25 guideline-making requires reform" published</p>
<p>Page 95</p> <p>1 MS. JOHNSTON: Object to the 2 form.</p> <p>3 QUESTIONS BY MR. TRACEY:</p> <p>4 Q. Yeah. 5 It's where it says, "Evaluation 6 of a number of guidelines have found that 7 many recommendations are based on low-quality 8 evidence and expert opinion. This is 9 particularly problematic as expert opinion is 10 subject to bias, either implicit or 11 subconscious."</p> <p>12 MS. JOHNSTON: Just wait for a 13 question.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. You agree, Doctor, that expert 16 opinion is the lowest of quality evidence?</p> <p>17 MS. JOHNSTON: Object to the 18 form.</p> <p>19 THE WITNESS: Yes, that is the 20 lowest quality of evidence in practice 21 bulletins.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. And one of the things -- well, 24 when you say this is particularly problematic 25 as expert opinion is subject to bias, either</p>	<p>Page 97</p> <p>1 in JAMA. 2 That's one article that you 3 cited, right?</p> <p>4 A. That is correct.</p> <p>5 Q. Number 4 is "Reassessment of 6 clinical practice guidelines: Go gently into 7 that goodnight." 8 That's another one that you 9 cited.</p> <p>10 A. That is correct.</p> <p>11 Q. Number 11 you cited in support 12 of that position was relations -- number 11, 13 "Relationships between authors of clinical 14 practice guidelines and the pharmaceutical 15 industry," and that also was published in 16 JAMA.</p> <p>17 All three of those were in 18 JAMA, right?</p> <p>19 A. That is correct.</p> <p>20 Q. JAMA is one of the premiere 21 scientific medical journals in the world, 22 isn't it?</p> <p>23 MS. JOHNSTON: Object to the 24 form.</p> <p>25 THE WITNESS: JAMA is a very</p>

<p style="text-align: right;">Page 98</p> <p>1 well-respected journal, yes.</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. And then number 12 you cited,</p> <p>4 "Detsky, sources of bias for authors of</p> <p>5 clinical practice guidelines."</p> <p>6 Right?</p> <p>7 A. Yes.</p> <p>8 Q. And the reason that's a problem</p> <p>9 is because the rank-and-file physicians rely</p> <p>10 on ACOG leaders to give them -- to put out</p> <p>11 practice bulletins and guidelines so that</p> <p>12 they can apply them in their clinical</p> <p>13 practice, right?</p> <p>14 MS. JOHNSTON: Object to the</p> <p>15 form.</p> <p>16 THE WITNESS: I would say they</p> <p>17 may rely. They don't always rely on</p> <p>18 ACOG guidelines, but they may rely on</p> <p>19 ACOG guidelines.</p> <p>20 QUESTIONS BY MR. TRACEY:</p> <p>21 Q. Well, you certainly put them</p> <p>22 out so that they have them to rely on if they</p> <p>23 choose to?</p> <p>24 MS. JOHNSTON: Object to the</p> <p>25 form.</p>	<p style="text-align: right;">Page 100</p> <p>1 not aware of the correct treatment,</p> <p>2 and that would be treatment of preterm</p> <p>3 labor, for instance.</p> <p>4 So the appropriate treatment of</p> <p>5 hypertension was under investigation</p> <p>6 at that time.</p> <p>7 So there's a number of</p> <p>8 conditions in obstetrics that we're</p> <p>9 still investigating as to what the</p> <p>10 best course of action would be.</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Okay. You go on to say, "Among</p> <p>13 the more than 700 specific recommendations</p> <p>14 issued over the past decade, 30 percent are</p> <p>15 level A guidelines based on good and</p> <p>16 consistent scientific evidence, 38 percent of</p> <p>17 recommendations are based on limited or</p> <p>18 inconsistent evidence, and 32 percent are</p> <p>19 based primarily on consensus and expert</p> <p>20 opinion."</p> <p>21 That's what you-all found?</p> <p>22 A. That's what we found, yes.</p> <p>23 Q. And the 32 percent based on</p> <p>24 consensus and expert opinion, that is the</p> <p>25 lowest quality of evidence?</p>
<p style="text-align: right;">Page 99</p> <p>1 THE WITNESS: That is correct.</p> <p>2 The objective is to educate the</p> <p>3 fellows of ACOG in the best care of --</p> <p>4 or the most optimal care for women and</p> <p>5 their families.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Yes.</p> <p>8 All right. Well, let's look</p> <p>9 and see what you found in your study. If we</p> <p>10 flip over to the discussion section on</p> <p>11 page 509, we get your results.</p> <p>12 It says, "Our findings suggest</p> <p>13 that only a third of the recommendations put</p> <p>14 forth by the college in their practice</p> <p>15 bulletins are based on high-quality,</p> <p>16 consistent scientific evidence."</p> <p>17 Was that a surprise to you,</p> <p>18 Doctor, at the time when you made this</p> <p>19 finding?</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: It was not really</p> <p>23 a surprise to me because there's a</p> <p>24 number of issues that we have in</p> <p>25 obstetrics and gynecology where we are</p>	<p style="text-align: right;">Page 101</p> <p>1 MS. JOHNSTON: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: That is the</p> <p>4 lowest quality of scientific evidence,</p> <p>5 yes.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Did you -- I don't think your</p> <p>8 paper explored why it is 32 percent of your</p> <p>9 practice bulletins were based on low quality</p> <p>10 evidence.</p> <p>11 Do you remember if you found</p> <p>12 out why?</p> <p>13 MS. JOHNSTON: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: I would have to</p> <p>16 read the entire article to be able to</p> <p>17 answer that because it's been some</p> <p>18 time ago. I don't remember if we said</p> <p>19 anything about the potential reasons</p> <p>20 why.</p> <p>21 MS. JOHNSTON: You can read it.</p> <p>22 THE WITNESS: Can I read it?</p> <p>23 MS. JOHNSTON: Uh-huh.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. Do you -- yeah. No, we don't</p>

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1 need to do that. I'm fairly certain the  
 2 answer is not in there, but if you knew  
 3 otherwise, I was going to give you an  
 4 opportunity to say so.  
 5 All right. Well, let's --  
 6 MS. JOHNSTON: Well, I'll just  
 7 object to counsel's statement, but if  
 8 you've got a question, that's fine.  
 9 Dr. D'Alton, if you --  
 10 MR. TRACEY: Yeah, no, I don't  
 11 have a question.  
 12 (D'Alton Exhibit 997 marked for  
 13 identification.)  
 14 QUESTIONS BY MR. TRACEY:  
 15 Q. The next exhibit I want to,  
 16 Ray, hand you is Exhibit 997.  
 17 This is an article called  
 18 "Financial ties between leaders of  
 19 influential US professional medical  
 20 associations and industry: Cross-sectional  
 21 study."  
 22 Are you familiar with this  
 23 study, Dr. D'Alton?  
 24 A. No, I am not.  
 25 Q. In your --

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1 MS. JOHNSTON: And, Sean,  
 2 we're getting a copy.  
 3 THE WITNESS: Sorry. We're  
 4 waiting to get a copy, Mr. Tracey.  
 5 QUESTIONS BY MR. TRACEY:  
 6 Q. Oh, sorry. Well, this question  
 7 I'm about to ask you doesn't have anything to  
 8 do with the article, so let me ask it.  
 9 Do you typically in your work  
 10 at Columbia or -- or even in your free time  
 11 spend time exploring issues for paid  
 12 scientific or journal articles that have been  
 13 published that look at the financial ties  
 14 between US professional medical associations  
 15 and industry?  
 16 MS. JOHNSTON: Object to the  
 17 form.  
 18 THE WITNESS: I -- your  
 19 question was, do I spend time thinking  
 20 about that during my free time or  
 21 at -- or at Columbia?  
 22 What I would say is that --  
 23 QUESTIONS BY MR. TRACEY:  
 24 Q. I didn't say thinking about it.  
 25 A. I apologize.

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1 Q. Let me ask --  
 2 A. Thank you.  
 3 Q. Yeah. No, that's good. If you  
 4 don't remember or --  
 5 A. Yeah.  
 6 Q. -- have a question, please tell  
 7 me.  
 8 So my question was, are you  
 9 familiar -- do you keep abreast of the  
 10 medical and scientific literature that  
 11 explores issues related to US professional  
 12 medical associations and industry, financial  
 13 ties between the two?  
 14 MS. JOHNSTON: Object to the  
 15 form.  
 16 THE WITNESS: No, I don't keep  
 17 abreast of the literature related  
 18 that -- to that topic.  
 19 I just shared with you in my  
 20 own work and for our department at  
 21 Columbia, we have an independent  
 22 process to industry and the trials  
 23 that we conduct.  
 24 So I'm certainly aware of  
 25 potential conflicts, but I don't keep

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1 abreast of the literature because I  
 2 believe we have a situation at  
 3 Columbia where we keep -- we keep  
 4 separate from the -- from industry.  
 5 We have complete editorial --  
 6 QUESTIONS BY MR. TRACEY:  
 7 Q. Well --  
 8 A. We have complete editorial  
 9 disassociation and complete editorial  
 10 freedom.  
 11 Q. My question was not about  
 12 Columbia, Dr. D'Alton.  
 13 My question was about US  
 14 professional medical associations and  
 15 industry.  
 16 You are a member of influential  
 17 US professional medical associations, are you  
 18 not?  
 19 MS. JOHNSTON: Object to the  
 20 form. Yeah.  
 21 MR. TRACEY: Let me ask --  
 22 MS. JOHNSTON: I don't know  
 23 what the question is.  
 24 MR. TRACEY: Yep.  
 25

<p style="text-align: right;">Page 106</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. You are, Doctor, a leader of</p> <p>3 influential US professional medical</p> <p>4 associations, are you not?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: I'm not a leader</p> <p>8 of those professional medical</p> <p>9 societies anymore. I used to have a</p> <p>10 role at the Society for Maternal-Fetal</p> <p>11 Medicine where I was a president, and</p> <p>12 I ran their foundation to do research</p> <p>13 and stimulate research in pregnancy.</p> <p>14 And I was very active in ACOG</p> <p>15 in many of their documents in the</p> <p>16 earlier parts of my career.</p> <p>17 More recently, my association</p> <p>18 with ACOG is here in New York where I</p> <p>19 lead -- co-lead the Safe Motherhood</p> <p>20 Initiative.</p> <p>21 So I don't have a leadership</p> <p>22 role in ACOG as a role or in SMFM as a</p> <p>23 role right now.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. But you have in the past?</p>	<p style="text-align: right;">Page 108</p> <p>1 THE WITNESS: It's a respected</p> <p>2 journal. I'm not sure of its impact</p> <p>3 factor, but it's a respected journal.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. All right. Under results of</p> <p>6 the study, there -- oops, down there, the</p> <p>7 abstract results. It says, "235 of 328</p> <p>8 leaders (72 percent), had financial ties to</p> <p>9 industry. Among 293 leaders who were medical</p> <p>10 doctors or doctors of osteopathy, 235 (or</p> <p>11 80 percent) had ties.</p> <p>12 "Total payments for 2017 to</p> <p>13 2019 leadership were almost \$130 million,</p> <p>14 with a median amount for each leader of</p> <p>15 \$31,000, interquartile range, 1157 to</p> <p>16 245,272.</p> <p>17 "General payments, including</p> <p>18 those for consultancy and hospitality, were</p> <p>19 24 million, and research payments were</p> <p>20 104 million -- \$104.6 million, predominantly</p> <p>21 payments to academic institutions with</p> <p>22 association leaders named as principal</p> <p>23 investigators."</p> <p>24 Did I read that correctly?</p> <p>25 MS. JOHNSTON: Object to the</p>
<p style="text-align: right;">Page 107</p> <p>1 A. That is correct, I have in the</p> <p>2 past, where I have -- I have been past</p> <p>3 president of SMFM. I've done the</p> <p>4 committees -- many committee opinions with</p> <p>5 ACOG, and I've been involved in many of their</p> <p>6 publications.</p> <p>7 Q. Okay. And just to -- for the</p> <p>8 record, we'll point out that this article</p> <p>9 we're about to explore was published in BMJ.</p> <p>10 That's the British Medical</p> <p>11 Journal, right?</p> <p>12 A. Okay.</p> <p>13 Q. Do you see that?</p> <p>14 A. Let me look here. Sorry. I'm</p> <p>15 just looking at the computer and looking at</p> <p>16 the -- at the exhibit. So just give me a</p> <p>17 moment.</p> <p>18 Q. At the bottom of the page, it</p> <p>19 says, "BMJ, 2020."</p> <p>20 A. Yes.</p> <p>21 Q. And the British Medical Journal</p> <p>22 is a highly respected medical journal,</p> <p>23 correct?</p> <p>24 MS. JOHNSTON: Object to the</p> <p>25 form.</p>	<p style="text-align: right;">Page 109</p> <p>1 form.</p> <p>2 THE WITNESS: You read it the</p> <p>3 way it is said here. That is correct.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. Have you been a principal</p> <p>6 investigator at Columbia?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And then if we go to the</p> <p>9 conclusions, it says, "Financial relationship</p> <p>10 between the leaders of influential US</p> <p>11 professional medical associations and</p> <p>12 industry are extensive, although with</p> <p>13 variation among the associations.</p> <p>14 "The quantum of payments raises</p> <p>15 questions about independence and integrity,</p> <p>16 adding weight to calls for policy reform."</p> <p>17 Ma'am, are you aware of the</p> <p>18 calls for policy reform with respect to</p> <p>19 financial ties between US professional</p> <p>20 medical associations and industry?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: I'm aware that's</p> <p>24 an issue. With calls for it, I can't</p> <p>25 say I'm specifically aware of who's</p>

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1 calling for what.

2 So I would -- I -- I'm aware of

3 the issue of influence of -- potential

4 influence of pharmaceutical -- the

5 pharmaceutical industry and

6 professions --

7 QUESTIONS BY MR. TRACEY:

8 Q. Are you --

9 A. -- professional medical

10 associations. Sorry.

11 MS. JOHNSTON: No. You can

12 finish your response, Dr. D'Alton.

13 QUESTIONS BY MR. TRACEY:

14 Q. Yeah, I'm sorry. Sorry about

15 that.

16 A. No worries.

17 Q. Are you -- yeah.

18 Are you calling for reform,

19 Doctor?

20 MS. JOHNSTON: Object to the

21 form.

22 THE WITNESS: I need to know

23 more about it to look into this. I

24 can -- I've just shared with you how

25 we've reformed things at Columbia with

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1 respect to US professional medical

2 associations.

3 I know that it is very much at

4 the forefront of ACOG and SMFM and

5 all -- and all conflicts must be

6 declared if you're working on a

7 practice bulletin, and there's -- and

8 you're not allowed to work on a

9 practice bulletin at ACOG if there is

10 a conflict of interest that's been

11 declared.

12 QUESTIONS BY MR. TRACEY:

13 Q. Are you sure about that?

14 MS. JOHNSTON: Object to the

15 form.

16 THE WITNESS: At the present

17 time, I understand that's the case,

18 yes.

19 QUESTIONS BY MR. TRACEY:

20 Q. When did that start?

21 MS. JOHNSTON: Object to the

22 form.

23 THE WITNESS: I don't remember

24 exactly when it started, but this

25 is -- there has been a continual

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1 process of improvement at ACOG and at

2 SMFM with their guidelines and how

3 they have arrived at their guidelines.

4 I'm not sure of the exact year when

5 that happened.

6 (D'Alton Exhibit 967 marked for

7 identification.)

8 QUESTIONS BY MR. TRACEY:

9 Q. Okay. Let's move on

10 Exhibit 967. This is a commentary by Adam

11 Wolfberg. I don't know if you know

12 Dr. Wolfberg. Do you or -- I don't know if

13 he's a doctor actually.

14 And the name of the commentary

15 is, "Conflict of interest related to clinical

16 practice is underreported: The case of

17 noninvasive prenatal testing."

18 Yeah, I'm sorry. He is a

19 doctor. He's a -- he's a maternal-fetal

20 medicine doctor, Dr. Wolfberg.

21 Do you know him?

22 A. I believe I've heard of him,

23 but I can't remember specifically at this

24 point.

25 Q. Okay. Let's read the abstract

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1 together. It says, "Authors of policy

2 statements from the American College of

3 Obstetricians and Gynecologists and from the

4 Society of Maternal-Fetal Medicine do not

5 acknowledge the potential for their clinical

6 income to influence their opinions or the

7 positions of the societies they represent."

8 Do you agree with that?

9 MS. JOHNSTON: Object to the

10 form.

11 THE WITNESS: I don't know the

12 basis for his -- for that statement.

13 I would have to look at it more

14 carefully. I don't know the basis for

15 that.

16 QUESTIONS BY MR. TRACEY:

17 Q. Well, he might tell us in the

18 next sentence.

19 It says, "These policy

20 statements were published in Obstetrics and

21 Gynecology in the American College of

22 Obstetricians and Gynecologists, again,

23 without acknowledgement of the potential for

24 conflict of interest.

25 "The case of noninvasive

<p style="text-align: right;">Page 114</p> <p>1 prenatal testing, which has threatened the 2 role of maternal-fetal medicine in the 3 practice of prenatal screening and diagnosis, 4 has significantly reduced the demand for 5 invasive prenatal diagnosis, illustrates the 6 importance of identifying this potential 7 conflict." 8 Do you know what he's speaking 9 of, Doctor? 10 MS. JOHNSTON: Object to the 11 form. 12 THE WITNESS: I don't know 13 specifically what he is -- what he is 14 speaking about. But certainly the 15 fact that these -- the statement that 16 he is saying here about the case of 17 noninvasive prenatal testing which has 18 threatened the role of maternal-fetal 19 medicine in the practice of prenatal 20 screening and diagnosis, I strongly 21 disagree with that portion of it 22 because it has completely changed 23 practice in prenatal diagnosis, 24 screening and diagnosis, and is 25 extremely well-accepted by patients.</p>	<p style="text-align: right;">Page 116</p> <p>1 '17, yes. 2 Q. Okay. Let's see what he says 3 in the first sentence. He says, "Concern 4 about conflict of interest in medicine dates 5 to at least the middle of the last century, 6 but the current paradigm for considering the 7 potential for financial incentives to 8 influence a physician's duty to put her 9 patient's best interests first may owe its 10 origin to a seminal 1984 editorial in the 11 New England Journal of Medicine entitled 'The 12 New Medical-Industrial Complex.'" 13 Are you familiar with that 14 article? 15 MS. JOHNSTON: Object to the 16 form. 17 THE WITNESS: No, I'm not 18 familiar with this article. At this 19 point. Have I ever read it? Maybe, 20 but I can't recall that at this point. 21 QUESTIONS BY MR. TRACEY: 22 Q. Okay. If we skip a sentence, 23 he goes on to say, "The concern three decades 24 ago is not substantially different from 25 concern today and can be defined as the</p>
<p style="text-align: right;">Page 115</p> <p>1 So I have no idea what he means 2 by "threatening the role of 3 maternal-fetal medicine." I think it 4 has enhanced the role of 5 maternal-fetal medicine and enhanced 6 our ability to be able to screen 7 accurately and make an appropriate 8 diagnosis through the use of 9 noninvasive prenatal testing. 10 QUESTIONS BY MR. TRACEY: 11 Q. Okay. Let's highlight the date 12 of this article because I -- I think that may 13 be important to his claim. This is -- this 14 is from October of 2017, about six years ago, 15 Doctor. 16 Do you see that? 17 A. Yes, I think -- 18 Q. Published -- 19 A. I think it was published in 20 2018 in Prenatal Diagnosis. 21 Q. Yeah, fair enough. 22 But it was written, it looks 23 like, and accepted in 2017, right? 24 A. It was accepted the -- I 25 believe it's the last day of September in</p>	<p style="text-align: right;">Page 117</p> <p>1 Institute of Medicine did in a 2009 report, 2 as, quote, 'A set of circumstances that 3 creates a risk that professional judgment or 4 actions regarding a primary interest will be 5 unduly influenced by a secondary interest.'" 6 Are you familiar with the 7 Institute of Medicine report that that is 8 derived from, that quote? 9 MS. JOHNSTON: I object to the 10 form. 11 THE WITNESS: I don't recall 12 that statement from the Institute of 13 Medicine. I'm not sure what it's 14 related to. 15 QUESTIONS BY MR. TRACEY: 16 Q. Okay. Do you understand that 17 to be -- the unduly influenced by a secondary 18 interest, do you understand that to be money? 19 MS. JOHNSTON: Object to the 20 form. 21 THE WITNESS: I'd need to look 22 at that report to know if that's what 23 they're talking about. 24 So I -- having not read that or 25 not -- maybe I have read it at some</p>

<p style="text-align: right;">Page 118</p> <p>1 point, but not having studied that</p> <p>2 right now, I don't know that that's</p> <p>3 what they are referring to.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. Okay. They go on to say that,</p> <p>6 "There are two broad categories of conflict</p> <p>7 of interest in medicine. The first, when</p> <p>8 payment for medical services influences the</p> <p>9 care a physician chooses to provide to her</p> <p>10 patient, was the subject of the Stark Laws,</p> <p>11 three laws passed by Congress between 1989</p> <p>12 and 1993, that largely prevented physician --</p> <p>13 physicians from referring patients to</p> <p>14 facilities that they own."</p> <p>15 And are you familiar with the</p> <p>16 history of those laws?</p> <p>17 MS. JOHNSTON: Object to the</p> <p>18 form.</p> <p>19 THE WITNESS: I'm not familiar</p> <p>20 with the history of the Stark Laws,</p> <p>21 but I'm familiar with the concept of</p> <p>22 the Stark Laws, which is that of</p> <p>23 self-referral, and that is not</p> <p>24 something that is considered to be an</p> <p>25 ethical practice.</p>	<p style="text-align: right;">Page 120</p> <p>1 familiar with that law?</p> <p>2 A. Yes, I am.</p> <p>3 MS. JOHNSTON: Object to the</p> <p>4 form.</p> <p>5 QUESTIONS BY MR. TRACEY:</p> <p>6 Q. You yourself are required to</p> <p>7 log payments that you received from</p> <p>8 pharmaceutical companies or industry on a</p> <p>9 website, correct?</p> <p>10 MS. JOHNSTON: Object to the</p> <p>11 form.</p> <p>12 THE WITNESS: I don't do it on</p> <p>13 a website. I report those conflicts</p> <p>14 of interest to my institution.</p> <p>15 QUESTIONS BY MR. TRACEY:</p> <p>16 Q. I see. Okay.</p> <p>17 Have you ever looked yourself</p> <p>18 up on the Open Payments website?</p> <p>19 A. Not recently, no, because I</p> <p>20 report my conflicts of interest.</p> <p>21 Q. Okay. Now, on the right</p> <p>22 paragraph there, the last sentence in the</p> <p>23 first paragraph, it says, "Although noted</p> <p>24 elsewhere, these journals" -- referring to</p> <p>25 ACOG, the Green and Gray journal.</p>
<p style="text-align: right;">Page 119</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Yes. And laws were enacted to</p> <p>3 prevent that --</p> <p>4 MS. JOHNSTON: Object to the</p> <p>5 form.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. -- right?</p> <p>8 A. That's the basis of the</p> <p>9 Stark Law, but I don't know the history of</p> <p>10 the Stark Law.</p> <p>11 Q. All right. They go on to say,</p> <p>12 "The second category of conflict of interest,</p> <p>13 when payments from companies (typically</p> <p>14 pharmaceutical or medical device companies)</p> <p>15 to physicians influence the care provided to</p> <p>16 a patient, the research findings of an</p> <p>17 investigator, or the publishes opinions of an</p> <p>18 author.</p> <p>19 "This category of conflict was</p> <p>20 addressed by Congress with the establishment</p> <p>21 of the Sunshine Act that requires all</p> <p>22 payments to physicians valued at \$10 or</p> <p>23 greater to be reported by companies that make</p> <p>24 or sell drugs or devices."</p> <p>25 And you, of course, are</p>	<p style="text-align: right;">Page 121</p> <p>1 "These journals have largely</p> <p>2 failed to identify conflicts of interest that</p> <p>3 exists when financial incentives related to</p> <p>4 an author's practice of medicine may</p> <p>5 influence their published findings or</p> <p>6 opinions, even though the impact of financial</p> <p>7 incentives on clinicians' behavior is</p> <p>8 well-documented."</p> <p>9 Are you familiar with what</p> <p>10 they're referring to in that sentence?</p> <p>11 MS. JOHNSTON: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: I think they're</p> <p>14 referring to what was in the previous</p> <p>15 sentence by PubMed search of articles</p> <p>16 in obstetrics and gynecology over the</p> <p>17 last decade.</p> <p>18 And let me just look at the</p> <p>19 references that they have shown.</p> <p>20 QUESTIONS BY MR. TRACEY:</p> <p>21 Q. Do you want to go through them,</p> <p>22 3 through 12?</p> <p>23 A. I'm just -- I'm just quickly</p> <p>24 answering them -- looking at -- excuse me,</p> <p>25 looking at them so I can answer your</p>

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1 question.  
 2 The way I read the references  
 3 that are stated here is that many of these  
 4 articles are related to robotic surgery and  
 5 surgery, and some are related to the benefits  
 6 of industry and their innovation in research  
 7 and clinical application of genetic prenatal  
 8 diagnosis.  
 9 So I don't think the way the  
 10 statement is said, that it is highlighting  
 11 the conflict of interest. Some of them,  
 12 particularly the article by Evans, looks at  
 13 the controversies in prenatal diagnosis,  
 14 industry drives innovation in research and  
 15 clinical application of genetic diagnosis and  
 16 screening, which I'm familiar with this, and  
 17 it has driven innovation substantially in  
 18 prenatal diagnosis and screening.  
 19 So it mentions some things  
 20 about conflicts of interest, but it doesn't  
 21 mention anything about the potential benefits  
 22 of pharmaceutical innovation in the field of  
 23 prenatal screening and diagnosis.  
 24 So I believe that is  
 25 misleading.

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1 Q. I see.  
 2 So you want to draw our  
 3 attention to the benefits of industry  
 4 dollars?  
 5 MS. JOHNSTON: I object to the  
 6 form.  
 7 THE WITNESS: I don't -- that's  
 8 not -- that's not what I'm responding  
 9 to. I'm responding to the articles  
 10 that were quoted here on extensive  
 11 focus of financial relationships  
 12 between investigators and  
 13 pharmaceutical and device companies,  
 14 which was referenced here.  
 15 And what I'm saying is that  
 16 many of those have been around robotic  
 17 surgery, but the one that he is  
 18 reporting on is noninvasive prenatal  
 19 testing.  
 20 And I for one know of the  
 21 amazing revolution that has occurred  
 22 in prenatal screening and diagnosis  
 23 because of innovation by specific  
 24 companies.  
 25 So that is not acknowledged as

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1 a benefit here, although it's  
 2 referenced.  
 3 QUESTIONS BY MR. TRACEY:  
 4 Q. Doctor, we're going to look at  
 5 it later.  
 6 Are you familiar with the  
 7 vaginal mesh disaster in your field?  
 8 MS. JOHNSTON: Object to the  
 9 form.  
 10 THE WITNESS: I'm an  
 11 obstetrician, and I practice OB and  
 12 maternal-fetal medicine, and I'm  
 13 certainly aware of the issues  
 14 related -- some of the issues related  
 15 to mesh, but it's not my specialty,  
 16 and I'm not up on all of the issues  
 17 surrounding this.  
 18 So I really don't believe I'm  
 19 qualified to answer that because I  
 20 don't practice gynecology.  
 21 QUESTIONS BY MR. TRACEY:  
 22 Q. Okay. Do you do  
 23 robotic-assisted surgery?  
 24 A. No, I don't do robotic-assisted  
 25 surgery. This here is about noninvasive

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1 prenatal testing, and I'm pretty familiar  
 2 with that.  
 3 Q. I thought you were drawing my  
 4 attention to robotic-assisted surgery  
 5 innovations.  
 6 A. Well, we -- there's no doubt  
 7 that is uncontested, that there's innovation  
 8 in robotic surgery, but the article by  
 9 Dr. Wolfberg here is related to the case of  
 10 noninvasive prenatal testing, and many of his  
 11 references are not related to that.  
 12 Q. Ah, I see.  
 13 Okay. All right. Well,  
 14 let's flip over to the next page and see what  
 15 he says.  
 16 He says, "Policy statements for  
 17 the American College of Obstetricians and  
 18 Gynecologists from the Society for  
 19 Maternal-Fetal Medicine regarding the role of  
 20 NIPT in obstetric practice were similarly  
 21 written by clinicians who failed to note  
 22 their conflict of interest related to their  
 23 practice.  
 24 "These statements were  
 25 published in Obstetrics and Gynecology and

<p style="text-align: right;">Page 126</p> <p>1 the American Journal of Obstetrics and 2 Gynecology. 3 "Fifteen of 23 members of the 4 ACOG committees and each of the 17 members of 5 the SMFM publications committee that authored 6 the policy statements practice maternal-fetal 7 medicine, a field that derives a significant 8 portion of its income from fetal ultrasound 9 examinations, including measurement of the 10 nuchal translucency that is part of most 11 aneuploidy screening tests that are performed 12 in the first trimester. 13 "Furthermore, traditional 14 aneuploidy screening tests generate follow-up 15 testing that is typically performed by 16 maternal-fetal medicine physicians." 17 Now, do you understand what 18 he's saying there, Dr. D'Alton? 19 MS. JOHNSTON: Object to the 20 form. 21 THE WITNESS: I think what he's 22 saying here is quite honestly 23 ridiculous because it means that no 24 maternal-fetal medicine physician 25 could comment -- who practiced</p>	<p style="text-align: right;">Page 128</p> <p>1 ultrasound. 2 So I have never during my 3 academic life put as a conflict, I 4 practice medicine and do ultrasound 5 and prenatal diagnosis. I feel that's 6 the practice of medicine and not a 7 conflict. 8 QUESTIONS BY MR. TRACEY: 9 Q. But I think what he's saying, 10 Doctor, to be fair, is the policy statements 11 pushing back on noninvasive prenatal testing 12 were written by those that had financial 13 incentives to push back on it something that 14 you quite candidly have acknowledged today is 15 accepted, right? 16 MS. JOHNSTON: Object to the 17 form. 18 THE WITNESS: I don't know what 19 you mean by pushing back on it. The 20 members of the ACOG committees, it 21 doesn't say who they are, and the 17 22 members of -- 23 QUESTIONS BY MR. TRACEY: 24 Q. Doctor -- 25 A. -- the publications committee,</p>
<p style="text-align: right;">Page 127</p> <p>1 clinical medicine could comment on 2 this. 3 So this is not about 4 relationships with industry. This is 5 what they do and what I -- we do in 6 our daily practice, which is the 7 practice of fetal ultrasound 8 examination. 9 So respectfully, I totally 10 disagree with this comment. 11 QUESTIONS BY MR. TRACEY: 12 Q. Well, what he's saying, though, 13 is that you can't comment -- he's saying that 14 when you comment, you better disclose your 15 financial interests, right? 16 MS. JOHNSTON: Object to the 17 form. 18 THE WITNESS: I mean, that is 19 disclosing essentially -- that's 20 saying the same as your financial 21 interests are that I practice 22 medicine. 23 Because that's what 24 obstetricians, gynecologists and 25 maternal-fetal medicine do who do</p>	<p style="text-align: right;">Page 129</p> <p>1 it doesn't say that. It says that they're 2 deriving a significant portion of their 3 income from fetal ultrasound examinations. 4 That means they're practicing medicine. I 5 don't know who else would be qualified to do 6 this. 7 Q. It's not a matter of who's 8 qualified, Doctor. It's whether you disclose 9 that your policy statement resisting -- 10 resisting the acceptance of noninvasive 11 prenatal testing, that when you write a 12 policy statement against new technology, you 13 should recognize that it is financially in 14 your interest to do so. That's the point. 15 MS. JOHNSTON: Wait for a 16 question. 17 (D'Alton Exhibit 921A marked 18 for identification.) 19 QUESTIONS BY MR. TRACEY: 20 Q. All right. Well, let's move on 21 to the next article. It's Exhibit 921A, 22 called "Evaluating financial conflicts of 23 interest among contributors to the clinical 24 practice guidelines of the American College 25 of Obstetricians and Gynecologists."</p>

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1 This was published in July  
 2 of 2020 in the journal of the American  
 3 Osteopathic Association.  
 4 By the way, Doctor, just as  
 5 sort of a threshold matter, do you believe  
 6 that these types of papers that evaluate  
 7 conflicts of interest among contributors to  
 8 clinical practice guidelines of ACOG are  
 9 helpful to the public?  
 10 MS. JOHNSTON: Object to the  
 11 form.  
 12 THE WITNESS: I would need to  
 13 know which one to comment on, but I  
 14 can tell you the last one was  
 15 unhelpful. I have no idea what the  
 16 benefit of that last one by  
 17 Dr. Wolfberg was.  
 18 Others -- you know, I don't  
 19 want to answer as a blanket statement.  
 20 We'll go through each one, and I can  
 21 give my comments about whether it's  
 22 useful or not.  
 23 QUESTIONS BY MR. TRACEY:  
 24 Q. So this one, if you just flip  
 25 down to the -- scroll down to the results

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1 section, it says, "General and research  
 2 payments were calculated among 65 physicians  
 3 in the Open Payments database: 44 physician  
 4 members of both the obstetrics and gynecology  
 5 practice bulletin committees, 4 2016 ACOG  
 6 executive board physician members, and 17  
 7 contributing physician authors.  
 8 "Research payments accounted  
 9 for greater than 78 percent of all payments.  
 10 Consulting, travel and lodging and speaking  
 11 fees totaled greater than \$90,000 and  
 12 contributed to more than 90 percent of the  
 13 total amount of general statements. Food and  
 14 beverage payments contributed to 10 percent  
 15 of all general payments. Three covered  
 16 members were noncompliant with the financial  
 17 conflict of interest guidelines, receiving  
 18 industry payments exceeding \$5,000."  
 19 Are you familiar with this  
 20 paper?  
 21 A. No, I'm --  
 22 MS. JOHNSTON: Object to the  
 23 form and object to the preamble.  
 24 THE WITNESS: I'm not familiar  
 25 with this paper.

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1 QUESTIONS BY MR. TRACEY:  
 2 Q. All right. Well, let's flip  
 3 over and see what these authors have to say.  
 4 A. Let me just see who they are.  
 5 Let me just see who they are first.  
 6 Q. Yeah, they're there. Let's  
 7 look.  
 8 A. Thank you.  
 9 Q. Micah Wright, Lance Frye,  
 10 Luanne Vo Solis, Jake Checketts, Carlos  
 11 Guevara, Larissa Smith and Matt Vassar.  
 12 It looks like they're at Center  
 13 for Health Sciences at Oklahoma State  
 14 University --  
 15 A. Got it.  
 16 Q. Obstetrics and Gynecology,  
 17 right? Do you know any of them?  
 18 A. I don't know any of them, no.  
 19 Q. All right. They say, "A  
 20 substantial body of evidence affirmed that  
 21 the" --  
 22 A. Where are we now? Oh, sorry.  
 23 Apologize. Okay. Got it.  
 24 Q. Top of the page.  
 25 A. Yeah.

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1 Q. "A substantial body of evidence  
 2 affirms the detrimental effects of financial  
 3 conflicts of interest, including their  
 4 influence on physicians' prescribing  
 5 practices and interpretation of clinical  
 6 results.  
 7 "A retrospective study of  
 8 industry payments to physicians found that  
 9 obstetrics and gynecology ranked fourth out  
 10 of 35 medical specialty for receipt of  
 11 industry payments to individual physicians."  
 12 Did you know that, ma'am?  
 13 MS. JOHNSTON: Object to the  
 14 form.  
 15 THE WITNESS: I did not know  
 16 that at this point, no.  
 17 QUESTIONS BY MR. TRACEY:  
 18 Q. Okay. So out of the 35  
 19 specialties, there's one, two -- there's  
 20 three above obstetrics and gynecology in  
 21 terms of total dollars paid to physicians  
 22 from industry, right?  
 23 MS. JOHNSTON: Object to the  
 24 form.  
 25

<p style="text-align: right;">Page 134</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Is that right, Doctor?</p> <p>3 A. That's what it states here. I</p> <p>4 have not had an opportunity to review the</p> <p>5 retrospective study that they're quoting.</p> <p>6 Q. Okay. I want to talk to you</p> <p>7 about clinical practice guidelines because</p> <p>8 that's what's in the middle of the page</p> <p>9 there.</p> <p>10 It says, "In the field of</p> <p>11 OB/GYN, standardization of practice is an</p> <p>12 important therapeutic goal due to widespread</p> <p>13 variability of clinical practice.</p> <p>14 Standardization of practice is critical to</p> <p>15 avoid repetitious errors within patient</p> <p>16 management. Clinical practice guidelines,</p> <p>17 CPGs, are created, in part, to improve</p> <p>18 standardization and encourage the delivery of</p> <p>19 evidence-based patient care. Limited</p> <p>20 evidence has suggested that a physician's</p> <p>21 adherence to CPG recommendations may be a</p> <p>22 basis for exoneration in lawsuits and may</p> <p>23 decrease the likelihood of attorneys taking</p> <p>24 up a particular lawsuit. On the other hand,</p> <p>25 failure to comply with CPGs may make a</p>	<p style="text-align: right;">Page 136</p> <p>1 they help in defining the standard of</p> <p>2 care, but it doesn't always help in</p> <p>3 the defining of the standard of care.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. So when they were available and</p> <p>6 they helped, did you use them?</p> <p>7 A. You know, as we've discussed</p> <p>8 this morning, I've done a number of</p> <p>9 depositions and trials, and I can't -- I</p> <p>10 can't recall at this point whether I used</p> <p>11 them when they helped. I may have referred</p> <p>12 to them, but I can't tell you at this point.</p> <p>13 But I don't define the standard</p> <p>14 of care based on a clinical practice</p> <p>15 guideline.</p> <p>16 Q. No, Doctor, but they certainly</p> <p>17 are used as evidence of what the standard of</p> <p>18 care is in medical negligence cases?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. Correct?</p> <p>23 A. I would not say it like that,</p> <p>24 Mr. Tracey. They're used as one portion of</p> <p>25 the evidence in -- of defining of standard of</p>
<p style="text-align: right;">Page 135</p> <p>1 physician -- make physicians culpable in</p> <p>2 malpractice litigation. The development --</p> <p>3 the development of CPGs under an ethically</p> <p>4 driven, transparent process, including a</p> <p>5 systematic review of the evidence, is highly</p> <p>6 desirable."</p> <p>7 So I have a few questions about</p> <p>8 that as a doctor who has testified in medical</p> <p>9 malpractice cases.</p> <p>10 Have you yourself used clinical</p> <p>11 practice guidelines to defend the conduct of</p> <p>12 doctors in medical malpractice cases?</p> <p>13 MS. JOHNSTON: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: What I use in</p> <p>16 medical malpractice cases is I</p> <p>17 determine whether the standard of care</p> <p>18 was met. And the standard of care is</p> <p>19 simply defined as what a -- the --</p> <p>20 what a reasonable obstetrician would</p> <p>21 do given a similar set of</p> <p>22 circumstances.</p> <p>23 And so in some instances,</p> <p>24 clinical guidelines may be applicable,</p> <p>25 and in others they may not be. So</p>	<p style="text-align: right;">Page 137</p> <p>1 care. They have input into the standard of</p> <p>2 care, but they're not the sole determinant of</p> <p>3 the standard of care.</p> <p>4 Q. For example, if a woman sued an</p> <p>5 obstetrician and said, you know what, you</p> <p>6 told me it was safe to take Tylenol during my</p> <p>7 pregnancy, and I had a child with severe</p> <p>8 autism, and I believe it was caused by</p> <p>9 Tylenol. If she was -- if she sued her</p> <p>10 obstetrician, an OB defending their conduct</p> <p>11 would very likely turn to the -- to the ACOG</p> <p>12 statement on Tylenol use in pregnancy,</p> <p>13 wouldn't they?</p> <p>14 MS. JOHNSTON: Object to the</p> <p>15 form.</p> <p>16 THE WITNESS: I really don't</p> <p>17 know what each person would do. They</p> <p>18 may go to the body of evidence, and</p> <p>19 they may go to the individual case to</p> <p>20 assess a patient's -- or that baby's</p> <p>21 risk for autism based on their genetic</p> <p>22 risk and what other -- what other</p> <p>23 comorbidities that were present in</p> <p>24 that mother and what was the outcome</p> <p>25 of the baby, whether it was a preterm</p>

<p style="text-align: right;">Page 138</p> <p>1 baby, whether it was neonatal</p> <p>2 encephalopathy.</p> <p>3 So I think various different</p> <p>4 clinical scenarios would go into</p> <p>5 that -- into that discussion and to</p> <p>6 that review.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. No doubt, Dr. D'Alton, all of</p> <p>9 that's probably true.</p> <p>10 But as a threshold matter,</p> <p>11 wouldn't the first thing that a doctor did or</p> <p>12 their lawyer is pick up the ACOG response to</p> <p>13 the consensus statement and wave it around</p> <p>14 for everybody to see?</p> <p>15 MS. JOHNSTON: I object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Look, I can't</p> <p>18 comment on what the first step a</p> <p>19 doctor would do or what a lawyer would</p> <p>20 do. That's up to each individual</p> <p>21 person.</p> <p>22 I'm just sharing with you what</p> <p>23 I would do in med mal, which is look</p> <p>24 at the entirety of the case and look</p> <p>25 at the risk factors, the background,</p>	<p style="text-align: right;">Page 140</p> <p>1 THE WITNESS: You know, I don't</p> <p>2 have knowledge whether ACOG ever did</p> <p>3 anything. You know, ACOG has many</p> <p>4 different outlets for making share</p> <p>5 statements and they're very active in</p> <p>6 media. They're very active in</p> <p>7 their -- in -- they're very active in</p> <p>8 the educational talks that are given</p> <p>9 by the different -- by the</p> <p>10 organization and by the meetings that</p> <p>11 are held by the different -- by the</p> <p>12 different subsections of ACOG.</p> <p>13 So have they ever weighed in?</p> <p>14 I don't know that.</p> <p>15 QUESTIONS BY MR. TRACEY:</p> <p>16 Q. You didn't -- certainly haven't</p> <p>17 cited anything other than their response to</p> <p>18 the consensus statement in your report?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: Yes. I -- I put</p> <p>22 in my report the -- their response</p> <p>23 that was requested by Dr. Bauer in the</p> <p>24 Bauer 2021 article with her 13</p> <p>25 authors.</p>
<p style="text-align: right;">Page 139</p> <p>1 the maternal risk, the paternal risk,</p> <p>2 and come up with a determination.</p> <p>3 QUESTIONS BY MR. TRACEY:</p> <p>4 Q. Well, do you know when the</p> <p>5 first epidemiology study associating Tylenol</p> <p>6 with neurodevelopmental disorders was</p> <p>7 published?</p> <p>8 MS. JOHNSTON: Object to the</p> <p>9 form.</p> <p>10 THE WITNESS: I think the first</p> <p>11 reported risk -- reported association,</p> <p>12 excuse me, was somewhere in the '80s.</p> <p>13 That's as best I recall.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. Okay.</p> <p>16 A. I can't be 100 percent</p> <p>17 confident of that at this point, but it's</p> <p>18 some time ago.</p> <p>19 Q. Do you know if before the</p> <p>20 consensus statement in 2021 was published, if</p> <p>21 ACOG ever weighed in on the issue of whether</p> <p>22 Tylenol can cause neurodevelopmental</p> <p>23 disorders?</p> <p>24 MS. JOHNSTON: Object to the</p> <p>25 form.</p>	<p style="text-align: right;">Page 141</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Yes.</p> <p>3 But I'm asking about other</p> <p>4 things that ACOG may have issued. Your</p> <p>5 report is devoid or lacking any other ACOG</p> <p>6 position paper.</p> <p>7 MS. JOHNSTON: Object to the</p> <p>8 form.</p> <p>9 QUESTIONS BY MR. TRACEY:</p> <p>10 Q. Is that true, or did I miss it?</p> <p>11 A. That is true for my report,</p> <p>12 yes, but I think your previous question was,</p> <p>13 have they ever weighed in, and I don't know</p> <p>14 the answer to that.</p> <p>15 Q. Okay.</p> <p>16 A. I have -- I don't -- yeah.</p> <p>17 Q. Okay. Down at the bottom of</p> <p>18 this article, the last sentence in the</p> <p>19 left-hand column says, "Some research would</p> <p>20 suggest that many obstetrics and</p> <p>21 gynecologists' practice bulletins contain</p> <p>22 recommendations based on low-quality</p> <p>23 evidence.</p> <p>24 "In particular, 37 percent of</p> <p>25 the practice bulletin recommendations is</p>

<p style="text-align: right;">Page 142</p> <p>1 based on expert opinion. Since expert  2 opinion has been shown to be subject to bias,  3 transparent and bias-limiting safeguards must  4 be adopted for writing and revising ACOG  5 practice bulletins."  6 Do you agree with that, ma'am?  7 MS. JOHNSTON: Object to the  8 form.  9 THE WITNESS: Yes. I think the  10 first one that you're quoting is a  11 reference to the article that was --  12 the lead author was Jason Wright, and  13 I'm a coauthor. So they're quoting  14 that, which I believe was published in  15 2011. This was a 2020 article. So,  16 to my knowledge, that has not been  17 updated.  18 And certainly I am aware that  19 ACOG has had many significant  20 improvements in how they're doing  21 their clinical practice guidelines and  22 have published on the methods that  23 they use for their clinical practice  24 guidelines.  25 So in my opinion, I would agree</p>	<p style="text-align: right;">Page 144</p> <p>1 it, in their response? They didn't disclose  2 who wrote it?  3 MS. JOHNSTON: Object to the  4 form.  5 THE WITNESS: They did not  6 write who wrote it in their report,  7 that is correct.  8 QUESTIONS BY MR. TRACEY:  9 Q. And there is no financial  10 disclosure or conflict of interest form  11 attached to that response that the world can  12 see, is there?  13 MS. JOHNSTON: Object to the  14 form.  15 THE WITNESS: I believe you are  16 correct in that.  17 QUESTIONS BY MR. TRACEY:  18 Q. So if all of the members of the  19 response to the consensus statement from ACOG  20 were doctors who had taken money from the  21 pharmaceutical industry, we are left without  22 knowing that, aren't we?  23 MS. JOHNSTON: Object to the  24 form.  25 THE WITNESS: We certainly</p>
<p style="text-align: right;">Page 143</p> <p>1 with that. A -- the way the -- first  2 of all, the article that Jason Wright  3 led was published by ACOG in their --  4 published in the ACOG journal. Excuse  5 me, I misspoke.  6 And also the way they conduct  7 doing practice bulletins -- or  8 clinical practice guidelines, excuse  9 me, has been now published and -- in  10 many different forums.  11 QUESTIONS BY MR. TRACEY:  12 Q. Can I ask you a question about  13 that?  14 A. Of course.  15 Q. Who were the ACOG members that  16 wrote the response to the consensus  17 statement?  18 MS. JOHNSTON: Object to the  19 form.  20 THE WITNESS: I'm not --  21 QUESTIONS BY MR. TRACEY:  22 Q. What are their names?  23 A. I'm not aware of who the ACOG  24 members were.  25 Q. And it wasn't disclosed, was</p>	<p style="text-align: right;">Page 145</p> <p>1 cannot say that with certainty, but I  2 would say the chances of that are  3 extremely low or approach zero from  4 what I know about the inner workings  5 of ACOG.  6 QUESTIONS BY MR. TRACEY:  7 Q. Well, then why not disclose it  8 and not make it a mystery?  9 MS. JOHNSTON: Object to the  10 form.  11 THE WITNESS: Well, I haven't  12 asked them that. I can't speak for  13 ACOG, but I certainly have worked with  14 ACOG for long enough that I have  15 enormous confidence in their  16 processes, and I have been extremely  17 impressed at the way they have  18 addressed their clinical practice  19 guidelines, has undergone such a  20 substantial change over the last  21 decade.  22 And now there is an  23 extraordinary detailed process done  24 in -- in publishing -- in the review,  25 the systematic review, the grading of</p>

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1 the evidence, and the recommendations  
2 that are given to the ACOG fellows.  
3 MR. TRACEY: I'm going to  
4 object to nonresponsive.  
5 QUESTIONS BY MR. TRACEY:  
6 Q. But, Dr. D'Alton, that  
7 extensive review is done in secret and is not  
8 disclosed to the public.  
9 MS. JOHNSTON: Object to the  
10 form.  
11 QUESTIONS BY MR. TRACEY:  
12 Q. Right?  
13 A. In my view, it is not done in  
14 secret. It is done by the ACOG staff and by  
15 the two -- and there's a publication that has  
16 stated, that is existing on the process for  
17 clinical practice guidelines by ACOG. So  
18 that is available to the public.  
19 Q. But the money that changes  
20 hands between industry and the authors of  
21 ACOG practice bulletins is not disclosed?  
22 MS. JOHNSTON: Object to the  
23 form.  
24 THE WITNESS: My information at  
25 the current time is that all members

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1 of a practice bulletin or a clinical  
2 practice guideline must disclose their  
3 conflicts of interests and will not be  
4 part of the review if they have a  
5 conflict of interest.  
6 QUESTIONS BY MR. TRACEY:  
7 Q. Who do they disclose them to?  
8 Not the public.  
9 MS. JOHNSTON: Object to the  
10 form.  
11 THE WITNESS: Well, they have  
12 to disclose them, usually, to their  
13 own institutions and to ACOG.  
14 QUESTIONS BY MR. TRACEY:  
15 Q. How much money does ACOG, as an  
16 organization, take from industry every year?  
17 MS. JOHNSTON: Object to the  
18 form.  
19 THE WITNESS: I am not aware of  
20 the arrangement, of the financial  
21 arrangements, between ACOG and  
22 industry.  
23 QUESTIONS BY MR. TRACEY:  
24 Q. Are you aware of the financial  
25 arrangements between the Society for

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1 Maternal-Fetal Medicine and industry, what  
2 percentage of their income is derived from  
3 industry?  
4 MS. JOHNSTON: Object to the  
5 form.  
6 THE WITNESS: I know that  
7 there's an industry policy with the  
8 Society for Maternal-Fetal Medicine,  
9 and how that is done, but I'm not  
10 aware of the current -- the current  
11 contribution of industry to the  
12 educational mission of the Society.  
13 QUESTIONS BY MR. TRACEY:  
14 Q. Okay.  
15 MS. JOHNSTON: Sean, I'm not  
16 trying to interrupt your flow, but  
17 we've been going another hour and  
18 change.  
19 MR. TRACEY: Can I just finish  
20 this paper and then we'll take a  
21 break?  
22 MS. JOHNSTON: Yep.  
23 MR. TRACEY: Yeah.  
24 QUESTIONS BY MR. TRACEY:  
25 Q. So under the Results section,

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1 let's just see what this study found.  
2 I'm sorry, it's about four  
3 pages in. 465.  
4 A. Where are we? Sorry. Results?  
5 Q. Yeah, Results section --  
6 A. Okay. Got it.  
7 Q. Okay. It says, "Of the 28" --  
8 "128 physicians identified, 65 were found to  
9 be listed in the Open Payments database as  
10 having received at least one form of general  
11 payment from an applicable manufacturer, and  
12 ten were listed as receiving specific  
13 research payments. Of the 65 physicians with  
14 payment data available, 44 were members of  
15 both the obstetrics and gynecology practice  
16 bulletin committees, four were members of the  
17 2016 ACOG executive board, and 17 contributed  
18 to the bulletins. 11 physicians were  
19 recorded as receiving greater than a thousand  
20 dollars in general payments, two received  
21 greater than \$5,000, and one received greater  
22 than \$10,000."  
23 Do you see that, ma'am?  
24 A. I do.  
25 Q. So two-thirds of the 65

<p style="text-align: right;">Page 150</p> <p>1 physicians who were receiving money from 2 industry were members of the obstetrics and 3 gynecology practice bulletin committees, 4 right?</p> <p>5 MS. JOHNSTON: Object to the 6 form.</p> <p>7 THE WITNESS: I mean, some of 8 this is not related to what they were 9 receiving individually because it's 10 stated in the results at the beginning 11 that research -- that 78 percent of 12 the payments were for research.</p> <p>13 So they may have not received 14 any direct monies towards them. It 15 may have gone to their institution.</p> <p>16 So I think it's important in 17 considering the elements of bias as to 18 what those payments were for, whether 19 there were -- they were to an 20 institution for research that had 21 nothing to do with that particular 22 practice guideline or practice 23 bulletin.</p> <p>24 So I really would need to know 25 a lot more about this to give a very</p>	<p style="text-align: right;">Page 152</p> <p>1 said I would need to look at all of 2 that in more detail to give a better 3 answer to you because I'm not aware 4 how many of those were in obstetrics 5 and gynecology journals, and I would 6 need to take a much more deep dive 7 review of that. That was written by a 8 single author, as I recall it, from 9 Queen's University.</p> <p>10 QUESTIONS BY MR. TRACEY: 11 Q. Epistemic corruption -- let me 12 see.</p> <p>13 By the way, on that subject, 14 has your institution, Columbia, ever 15 undertaken any research to discover biases 16 that may exist at Columbia with respect to 17 accepting industry dollars?</p> <p>18 MS. JOHNSTON: Object to the 19 form.</p> <p>20 THE WITNESS: I can't say about 21 any research, but there is an 22 organization that I was a part of at 23 Columbia called the -- I believe it 24 was called the Institute or -- of 25 Medicine at Columbia that was led by a</p>
<p style="text-align: right;">Page 151</p> <p>1 reasoned opinion on it.</p> <p>2 QUESTIONS BY MR. TRACEY: 3 Q. Dr. D'Alton, is it your opinion 4 that when the pharmaceutical industry funds 5 or finances somebody's career research that 6 that doesn't create any bias?</p> <p>7 MS. JOHNSTON: Object to the 8 form.</p> <p>9 THE WITNESS: You know, I would 10 never say never and never say always.</p> <p>11 What I will say is that from 12 what I know is of the reputable 13 institutions that I'm aware of, that 14 there's complete editorial 15 independence from a pharmaceutical 16 industry.</p> <p>17 QUESTIONS BY MR. TRACEY: 18 Q. But we saw in the first paper I 19 showed you about epistemic corruption that 20 the Cochrane review said in spite of all of 21 that, the bias still existed.</p> <p>22 Remember that?</p> <p>23 MS. JOHNSTON: Object to the 24 form.</p> <p>25 THE WITNESS: I do, and I also</p>	<p style="text-align: right;">Page 153</p> <p>1 wonderful epidemiologist who sadly 2 passed away, Dr. Rothman.</p> <p>3 QUESTIONS BY MR. TRACEY: 4 Q. Doctor, my question was about 5 studies and funding of studies. Not about 6 wonderful investigators.</p> <p>7 A. Okay. I --</p> <p>8 MS. JOHNSTON: I -- I'm sorry, 9 Sean, you asked her a question, and 10 she was attempting to answer it. I 11 think that that's --</p> <p>12 MR. TRACEY: She was not. She 13 was not. She was filibustering and --</p> <p>14 MS. JOHNSTON: I'm sorry, no, 15 Sean, we're not doing this. No, we're 16 not doing this. You don't -- if you 17 don't want her to answer the question 18 that you're asking, which may require 19 more than just a "yes" or "no" that 20 you want, she's going to be allowed to 21 do that.</p> <p>22 We're not going to do this. 23 You've interrupted her so many times 24 today.</p> <p>25 MR. TRACEY: She's not going to</p>

<p style="text-align: right;">Page 154</p> <p>1 do this live at trial, Sarah. I</p> <p>2 don't -- you better get her used to it</p> <p>3 now.</p> <p>4 MS. JOHNSTON: Sean, that's an</p> <p>5 absolutely absurd thing to say, but</p> <p>6 this is now the sixth time that you've</p> <p>7 asked a question, she started to</p> <p>8 answer it, you've interrupted because</p> <p>9 you don't like the way that she's</p> <p>10 answering it, but she very much is.</p> <p>11 We've got the realtime --</p> <p>12 MR. TRACEY: All of that may be</p> <p>13 true, but I only have so much time.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. But let me ask you this,</p> <p>16 Dr. D'Alton.</p> <p>17 Have you ever heard the saying</p> <p>18 "don't bite the hand that feeds"?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 Sean, you said that we were</p> <p>22 going to finish up this paper and then</p> <p>23 we're going to take a break.</p> <p>24 Let's take a break. That</p> <p>25 wasn't a real question --</p>	<p style="text-align: right;">Page 156</p> <p>1 what -- bite the hand that feeds in</p> <p>2 terms of conflict of interest in</p> <p>3 research.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. You would not?</p> <p>6 A. No, absolutely not.</p> <p>7 Q. Can you -- can you understand</p> <p>8 how others might?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 Is this about this paper?</p> <p>12 What --</p> <p>13 THE WITNESS: Others might. I</p> <p>14 don't know what others would do. I</p> <p>15 can't -- you know, I can't get into</p> <p>16 anyone's head and decide what they</p> <p>17 would do.</p> <p>18 MR. TRACEY: Okay. All right.</p> <p>19 Let's take a break.</p> <p>20 Can we do a real five minutes</p> <p>21 this time?</p> <p>22 MS. JOHNSTON: No, we're going</p> <p>23 to do ten.</p> <p>24 MR. TRACEY: Okay. All right.</p> <p>25 Ten is fine.</p>
<p style="text-align: right;">Page 155</p> <p>1 MR. TRACEY: We are. This --</p> <p>2 MS. JOHNSTON: Doctor --</p> <p>3 MR. TRACEY: -- is just</p> <p>4 finishing up this paper.</p> <p>5 MS. JOHNSTON: Then finish it.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Doctor, have you ever heard</p> <p>8 that term?</p> <p>9 A. I've heard that from -- since I</p> <p>10 was a little girl in Ireland where I was told</p> <p>11 to look after my parents.</p> <p>12 Q. And don't bite the hand that</p> <p>13 feeds, right?</p> <p>14 MS. JOHNSTON: Object to the</p> <p>15 form.</p> <p>16 THE WITNESS: I committed to</p> <p>17 always being there for them, so that's</p> <p>18 where I've heard it in that context.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. Can you think of another</p> <p>21 context that's relevant to what you and I</p> <p>22 have been discussing?</p> <p>23 MS. JOHNSTON: Object to the</p> <p>24 form.</p> <p>25 THE WITNESS: I would never use</p>	<p style="text-align: right;">Page 157</p> <p>1 MS. JOHNSTON: Yeah.</p> <p>2 VIDEOGRAPHER: The time right</p> <p>3 now is 11:42 a.m. We are off the</p> <p>4 record.</p> <p>5 (Off the record at 11:42 a.m.)</p> <p>6 VIDEOGRAPHER: The time right</p> <p>7 now is 11:58 a.m. We are back on the</p> <p>8 record.</p> <p>9 QUESTIONS BY MR. TRACEY:</p> <p>10 Q. Dr. D'Alton, you have been to</p> <p>11 the annual meeting of the Society for</p> <p>12 Maternal-Fetal Medicine in the past, correct?</p> <p>13 A. Yes, I believe I've been there</p> <p>14 every year since its inception, except for</p> <p>15 one.</p> <p>16 (D'Alton Exhibit 968 marked for</p> <p>17 identification.)</p> <p>18 QUESTIONS BY MR. TRACEY:</p> <p>19 Q. Okay. Ray, can you bring up</p> <p>20 Exhibit 968?</p> <p>21 Dr. D'Alton, I got my hands on</p> <p>22 a brochure for a Society for Maternal-Fetal</p> <p>23 Medicine Annual Pregnancy meeting from 2018.</p> <p>24 This meeting took place over, I guess, six</p> <p>25 days in Dallas, Texas --</p>

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1 MS. JOHNSTON: Hang on. Hang  
2 on, Sean. Sorry. We -- this is not  
3 the -- I think we have 968A.  
4 MR. TRACEY: Well, maybe --  
5 MS. JOHNSTON: This is a public  
6 access document.  
7 MR. TRACEY: Yeah, that's not  
8 it. I'm looking -- this is a long --  
9 this is what's on the screen is what  
10 I'm looking for.  
11 THE WITNESS: Sir, just give us  
12 a minute here. No, we got the same  
13 one.  
14 MR. TRACEY: So, Danny, they're  
15 saying they don't have the right one.  
16 (Off the record discussion.)  
17 QUESTIONS BY MR. TRACEY:  
18 Q. Let me ask this. Do you have  
19 in front of you what's on the screen?  
20 A. Yes, I can see what's on the  
21 screen here.  
22 MS. JOHNSTON: We don't  
23 have a -- we don't have a hard copy of  
24 it, though, Sean.  
25 MR. TRACEY: Yeah, I don't -- I

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1 don't know why.  
2 VIDEOGRAPHER: I've got 168.  
3 MR. TRACEY: I've got it as 968  
4 is my document.  
5 MS. JOHNSTON: I don't think  
6 he's saying A. I think he's saying  
7 968.  
8 MR. TRACEY: No A.  
9 MS. JOHNSTON: Yeah. All  
10 right. We're getting a copy.  
11 MR. TRACEY: Okay.  
12 MS. JOHNSTON: Yeah, we got it.  
13 QUESTIONS BY MR. TRACEY:  
14 Q. All right. Let me start again.  
15 Doctor, this is a brochure from  
16 the annual meeting of the Society of  
17 Maternal-Fetal Medicine from 2018, which took  
18 place in Dallas, Texas, and it's about 57  
19 pages long.  
20 Do you have that in front of  
21 you now?  
22 A. Yes, I do.  
23 Q. And I think we're going to find  
24 here in a minute that you were actually at  
25 this meeting.

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1 Do you remember this meeting?  
2 A. I don't remember the specifics  
3 of the meeting, but I remember being in  
4 Dallas in 2018, yes.  
5 Q. Okay. And these meetings take  
6 place typically in hotels, right?  
7 MS. JOHNSTON: Object to the  
8 form.  
9 THE WITNESS: They used to, but  
10 now they're more frequently at -- as  
11 the Society has grown, I believe  
12 they're more at conference centers.  
13 QUESTIONS BY MR. TRACEY:  
14 Q. Okay. This one says it was at  
15 the Hilton Anatole in Dallas, Texas, correct?  
16 A. That's what it states here,  
17 yes.  
18 Q. And who comes to these  
19 meetings, Doctor?  
20 MS. JOHNSTON: Object to the  
21 form.  
22 THE WITNESS: A variety of  
23 people come to the meetings. It's,  
24 first of all, for the members of the  
25 Society for Maternal-Fetal Medicine.

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1 Then there's a group of international  
2 members that -- many who are at the  
3 meeting. Then there's fellows and  
4 residents who are aspiring to be  
5 maternal-fetal medicine physicians or  
6 thinking -- certainly residents that  
7 are certainly thinking about it and  
8 fellows who are in the process of  
9 becoming a maternal-fetal medicine  
10 physician.  
11 Then there's invited speakers  
12 who come to the meeting. And then  
13 there's -- not usually to the meeting  
14 itself, but to the -- to the exhibit  
15 floor are a number of exhibitors.  
16 QUESTIONS BY MR. TRACEY:  
17 Q. And when you say exhibitors, do  
18 you mean industry?  
19 MS. JOHNSTON: Object to the  
20 form.  
21 THE WITNESS: Some would be  
22 industry, and some would be the  
23 hospitals who are -- and departments  
24 who have special programs and may want  
25 to showcase or increase the knowledge

<p style="text-align: right;">Page 162</p> <p>1 of their programs to other fellows who</p> <p>2 are at the meeting.</p> <p>3 QUESTIONS BY MR. TRACEY:</p> <p>4 Q. So some of the exhibitors, do</p> <p>5 they sometimes call them vendors?</p> <p>6 A. Vendors. I usually call them</p> <p>7 exhibitors, but vendors or exhibitors. I can</p> <p>8 use either one.</p> <p>9 Q. Okay. And I think they're</p> <p>10 going to be in here as both, but when we say</p> <p>11 "vendor" or "exhibitor," I can use those</p> <p>12 interchangeably with you?</p> <p>13 MS. JOHNSTON: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: Well --</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. Is that right?</p> <p>18 A. I mean, you can, but what I've</p> <p>19 said is that exhibitors could be from</p> <p>20 departments, and I would not consider them as</p> <p>21 vendors.</p> <p>22 Q. That's -- that's a good point.</p> <p>23 So let's not use them interchangeably.</p> <p>24 Some of the exhibitors will be</p> <p>25 from the pharmaceutical industry, right?</p>	<p style="text-align: right;">Page 164</p> <p>1 places in the hotel where there are</p> <p>2 places designated for the exhibitors.</p> <p>3 QUESTIONS BY MR. TRACEY:</p> <p>4 Q. Yeah, I'm talking about the</p> <p>5 exhibit floor. You just -- you've got to let</p> <p>6 me get there.</p> <p>7 So there are exhibit floors</p> <p>8 where exhibitors, including pharmaceutical</p> <p>9 companies and device companies, have booths,</p> <p>10 right?</p> <p>11 A. That's correct.</p> <p>12 Q. And in these booths, they have</p> <p>13 people, right?</p> <p>14 A. Yes.</p> <p>15 Q. And these are employees of the</p> <p>16 pharmaceutical industry or medical device</p> <p>17 industry who are there to sell things?</p> <p>18 MS. JOHNSTON: Object to the</p> <p>19 form.</p> <p>20 QUESTIONS BY MR. TRACEY:</p> <p>21 Q. Right?</p> <p>22 A. Well, I don't know their</p> <p>23 objective is whether to sell things or to</p> <p>24 share with -- share with the members what</p> <p>25 their products are, so they could become more</p>
<p style="text-align: right;">Page 163</p> <p>1 A. Yes. I'd have to take a look</p> <p>2 and see who they are, if they're mentioned</p> <p>3 here.</p> <p>4 Q. We're going to do that</p> <p>5 together, though. Just generally speaking, I</p> <p>6 want to talk about your experience.</p> <p>7 Some of the exhibitors will be</p> <p>8 from medical device companies, right?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: That's correct.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. And these medical device</p> <p>14 companies and these pharmaceutical companies,</p> <p>15 there are places in these conference centers</p> <p>16 or these hotels that are dedicated to the</p> <p>17 exhibitors, right?</p> <p>18 MS. JOHNSTON: Object to the</p> <p>19 form.</p> <p>20 THE WITNESS: I'm not</p> <p>21 aware of -- I'm -- sorry. Just let me</p> <p>22 be clear.</p> <p>23 On the exhibit floor, there are</p> <p>24 places that are designated for</p> <p>25 exhibitors. I'm not aware of other</p>	<p style="text-align: right;">Page 165</p> <p>1 knowledgeable about these products or they --</p> <p>2 the fellows and the members of the Society</p> <p>3 for Maternal-Fetal Medicine could become more</p> <p>4 knowledgeable about their products.</p> <p>5 Q. Yes.</p> <p>6 We have seasoned doctors, we</p> <p>7 have doctors in training, and we have young</p> <p>8 doctors all there that can go to the exhibit</p> <p>9 floor and talk to pharmaceutical companies</p> <p>10 and device companies that have products that</p> <p>11 they sell, right?</p> <p>12 MS. JOHNSTON: Object to the</p> <p>13 form.</p> <p>14 THE WITNESS: Yes, that's</p> <p>15 correct.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. And they will have brochures</p> <p>18 and materials that they hand out to any</p> <p>19 doctors or fellows or trainees that they</p> <p>20 may -- that may be interested, right?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: They may have a</p> <p>24 certain number of those brochures and</p> <p>25 information, yes.</p>

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1 QUESTIONS BY MR. TRACEY:

2 Q. And then these companies,

3 industry, will sometimes host happy hours,

4 right?

5 MS. JOHNSTON: Object to the

6 form.

7 THE WITNESS: I don't know that

8 they're called happy hours, but they

9 may host events for the -- for

10 different members of the Society.

11 QUESTIONS BY MR. TRACEY:

12 Q. And these are -- these are

13 casual events where wine and beer and things

14 like that are served, right?

15 MS. JOHNSTON: Object to the

16 form.

17 THE WITNESS: They're -- there

18 certainly are events of relaxation at

19 these meetings, yes.

20 QUESTIONS BY MR. TRACEY:

21 Q. And that gives, in a relaxed

22 atmosphere, an opportunity for these seasoned

23 doctors, fellows, residents, trainees, to

24 meet and mingle with members of industry,

25 right?

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1 MS. JOHNSTON: Object to the

2 form.

3 THE WITNESS: It is -- they are

4 given that opportunity. I find more

5 frequently they'll mingle more with

6 each other rather than industry, but

7 some certainly may mingle with

8 industry.

9 QUESTIONS BY MR. TRACEY:

10 Q. And then sometimes industry

11 will have industry-sponsored lunches or

12 dinners where seasoned doctors, experienced

13 doctors, trainees and fellows can literally

14 go get a free lunch, right?

15 MS. JOHNSTON: Object to the

16 form.

17 THE WITNESS: I don't know if

18 the lunch free. I thought we paid for

19 the lunch at the meeting, but it is

20 possible that these lunches agree --

21 those lunches happen.

22 I can't recall the specifics of

23 that at this time.

24 QUESTIONS BY MR. TRACEY:

25 Q. Well, in any event, you've been

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1 to these lunches or dinners,

2 industry-sponsored at these annual meetings,

3 right?

4 A. I've been to very few

5 industry-sponsored dinners at the annual

6 meeting because I'm usually too busy. I am

7 invited to a lot, but I'm certain -- I

8 probably have been at one or two of them.

9 But over the years I've been at

10 very few because I have a lot of colleagues

11 at the meetings, internationally and here in

12 the US, and that I have engagements with.

13 So can I say I've never been

14 there? No, but it would be fairly rare for

15 me to be at an industry dinner.

16 Q. And have you -- are you aware

17 of things like industry-sponsored golf

18 outings?

19 MS. JOHNSTON: Object to the

20 form.

21 THE WITNESS: I'm aware that

22 there are industry-sponsored golf

23 outings. Whether they occur at this

24 meeting or not, I don't know.

25

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1 QUESTIONS BY MR. TRACEY:

2 Q. You certainly have seen those

3 meetings, those outings advertised at

4 professional meetings for doctors and

5 residents and fellows to participate in?

6 MS. JOHNSTON: Object to the

7 form.

8 THE WITNESS: I'm not sure that

9 I have. I don't know whether I have

10 or I have not because I'm not a

11 golfer, so I probably wouldn't pay

12 much attention to it. I may or may

13 not have seen them.

14 QUESTIONS BY MR. TRACEY:

15 Q. What about industry-sponsored

16 events like going to a play or a show?

17 MS. JOHNSTON: Object to the

18 form.

19 THE WITNESS: There may be. I

20 don't know that there's many plays or

21 shows in Dallas, but -- that's usually

22 in Vegas, but I'm not aware of

23 industry-sponsored shows in Dallas.

24 So -- I think it's what we're

25 specifically talking about here.

<p style="text-align: right;">Page 170</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. You're aware of</p> <p>3 industry-sponsored shows in Las Vegas,</p> <p>4 though?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: I'm aware that</p> <p>8 there has been industry-sponsored</p> <p>9 shows in Las Vegas, and I know that</p> <p>10 the Society does no longer go or ACOG</p> <p>11 no longer goes to Vegas.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. Why?</p> <p>14 A. I'm not sure --</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: I'm not sure of</p> <p>18 the exact reasoning why they don't go</p> <p>19 there, but I know that they've made a</p> <p>20 decision -- at least the last time I</p> <p>21 was involved in these decision-makings</p> <p>22 was that Vegas was not a place where</p> <p>23 they would be considered.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. When did that end?</p>	<p style="text-align: right;">Page 172</p> <p>1 So it is available online, but</p> <p>2 I think because of the expense related</p> <p>3 to production of these documents, they</p> <p>4 were not given to members when they</p> <p>5 registered. I'm not sure of the year</p> <p>6 that was stopped, but I certainly know</p> <p>7 it's been in the last few years.</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. Okay. Well, the second page on</p> <p>10 the one I got, the second page is marketing</p> <p>11 material from an industry -- from someone in</p> <p>12 the industry, right, a company?</p> <p>13 A. Yes.</p> <p>14 Q. And then flip over, the next</p> <p>15 page -- oh, by the way, they say, "Visit us,"</p> <p>16 I think -- do they have the booth -- yeah,</p> <p>17 "Visit us" -- "visit Natera, booth 161."</p> <p>18 So you know where to go get --</p> <p>19 where in the exhibit hall or floor to go find</p> <p>20 them, right?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: That's what it</p> <p>24 states here, yes.</p> <p>25</p>
<p style="text-align: right;">Page 171</p> <p>1 MS. JOHNSTON: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: I can't recall</p> <p>4 the year at this point, but it's been</p> <p>5 some time since we've been in Vegas</p> <p>6 for a meeting.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. Okay. If we flip over the</p> <p>9 second page, up in the top right-hand corner,</p> <p>10 the first thing we see after the introduction</p> <p>11 is marketing materials from a company called</p> <p>12 Panorama, next generation NIPT, which is</p> <p>13 noninvasive prenatal testing, right?</p> <p>14 A. Yes, NIPT.</p> <p>15 Q. Yeah.</p> <p>16 So this brochure that I've got</p> <p>17 is something that's available on the Internet</p> <p>18 and it's also handed out to members or</p> <p>19 attendees when they register, correct?</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: I'm not sure if</p> <p>23 it's handed out. It's available</p> <p>24 online because we stopped giving the</p> <p>25 booklet out to attendings.</p>	<p style="text-align: right;">Page 173</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. And if you flip over the next</p> <p>3 page, it's somebody down the street here from</p> <p>4 me, UT -- UT-Houston, the Health Science</p> <p>5 Center at UT. They've got themselves some</p> <p>6 marketing materials with a visit us at</p> <p>7 booth 300, right?</p> <p>8 MS. JOHNSTON: Object to the</p> <p>9 form.</p> <p>10 THE WITNESS: That's correct.</p> <p>11 That's just like I was saying before,</p> <p>12 different departments will have</p> <p>13 exhibits at the annual meeting in</p> <p>14 certain instances.</p> <p>15 QUESTIONS BY MR. TRACEY:</p> <p>16 Q. And one of the things these</p> <p>17 medical schools do is they want to attract</p> <p>18 young talent, right?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: Absolutely.</p> <p>22 Recruiting and retaining is one of our</p> <p>23 main objectives.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. It's a big deal, isn't it?</p>

<p style="text-align: right;">Page 174</p> <p>1 MS. JOHNSTON: Same objection.</p> <p>2 THE WITNESS: It's -- I think</p> <p>3 it -- for me, it's a big deal. I</p> <p>4 spend a lot of time recruiting and</p> <p>5 retaining physicians.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Okay. And do you know whether</p> <p>8 or not it costs more to get the very first</p> <p>9 marketing position in this bulletin? Do you</p> <p>10 know that?</p> <p>11 MS. JOHNSTON: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: I don't know</p> <p>14 that.</p> <p>15 QUESTIONS BY MR. TRACEY:</p> <p>16 Q. Okay. Who puts together</p> <p>17 this -- this set of materials for the -- for</p> <p>18 the annual meetings? Do you know?</p> <p>19 A. I know something about the</p> <p>20 process. The details now, I'm not as</p> <p>21 familiar with because I haven't been a --</p> <p>22 since I was past president of the Society, I</p> <p>23 was involved, as I shared with you, in the</p> <p>24 foundation.</p> <p>25 So this is a publication by the</p>	<p style="text-align: right;">Page 176</p> <p>1 times today, from -- you were -- you were the</p> <p>2 president in 1998?</p> <p>3 A. That's correct.</p> <p>4 Q. All right. And then, you know,</p> <p>5 you sort of just keep flipping over, you'll</p> <p>6 see another advertisement.</p> <p>7 And then on page 6, you'll see</p> <p>8 sort of the welcome part of the materials.</p> <p>9 They say, you know, "Dear friends and</p> <p>10 colleagues."</p> <p>11 Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. And then down at the bottom,</p> <p>14 the last sentence on the page to the far</p> <p>15 right, it says, "We also hope," and then you</p> <p>16 got to flip over to --</p> <p>17 A. Sorry, okay. Just give me a</p> <p>18 minute here. Okay. Thank you.</p> <p>19 Q. "We also hope to see you at the</p> <p>20 grand opening reception, sponsored by</p> <p>21 Illumina, on Wednesday evening. Other</p> <p>22 events of note are an Illumina-sponsored</p> <p>23 dinner symposium on Tuesday evening, as well</p> <p>24 as industry learning lunches on Thursday</p> <p>25 (Sage) and on Friday (Natera)."</p>
<p style="text-align: right;">Page 175</p> <p>1 Gray journal, the American Journal of</p> <p>2 Obstetrics and Gynecology, and there would be</p> <p>3 input into this by the scientific program</p> <p>4 committee of the Society and the staff at the</p> <p>5 Society for Maternal-Fetal Medicine.</p> <p>6 That's really all I know</p> <p>7 about the -- at this point about the process</p> <p>8 and how this is put together.</p> <p>9 Q. Okay. And if you flip over to</p> <p>10 page 4, we'll see your name twice, and the</p> <p>11 pages are in the lower left-hand corner, and</p> <p>12 then sometimes they go to the right. It's</p> <p>13 not really -- I don't know why.</p> <p>14 But there we have you, Mary</p> <p>15 D'Alton, MD, ex officio, for the Foundation</p> <p>16 for the Society of Maternal-Fetal Medicine,</p> <p>17 right?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. You're on the board of</p> <p>20 directors at the time?</p> <p>21 A. Ex officio on the board of</p> <p>22 directors, yes.</p> <p>23 Q. Ex officio.</p> <p>24 And then we see you as past</p> <p>25 president down below, as you've said a few</p>	<p style="text-align: right;">Page 177</p> <p>1 Did I read that correctly?</p> <p>2 A. Yes, you've read that</p> <p>3 correctly.</p> <p>4 Q. So we have a grand opening</p> <p>5 reception. That's where the drinks are</p> <p>6 provided by Illumina, right, and hor</p> <p>7 d'oeuvres?</p> <p>8 MS. JOHNSTON: Object to the</p> <p>9 form.</p> <p>10 THE WITNESS: It's sponsored by</p> <p>11 Illumina. Now, whether it's payment</p> <p>12 for the entire event, I just don't</p> <p>13 know.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. Well, "sponsored by" means paid</p> <p>16 for, right?</p> <p>17 MS. JOHNSTON: Same objection.</p> <p>18 THE WITNESS: I mean, sometimes</p> <p>19 sponsorship is a contribution towards</p> <p>20 it and in -- when I've dealt with</p> <p>21 sponsorship, but whether it's total</p> <p>22 sponsorship or not, I really don't</p> <p>23 know.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. Well, you used the term</p>

<p style="text-align: right;">Page 178</p> <p>1 "sponsor" -- you objected to my term of --  2 when I said money exchanged hands with  3 respect to funding, and you said they were --  4 I thought you used the term "funding" or  5 "sponsorship" of your studies.  6 Did I -- did I hear that wrong?  7 MS. JOHNSTON: Object to the  8 form.  9 THE WITNESS: Well, you heard  10 part of that wrong. I didn't say  11 sponsorship of my studies. I said  12 funding of my studies.  13 QUESTIONS BY MR. TRACEY:  14 Q. Okay. Have you heard the term  15 "sponsorship bias" before?  16 A. Again, I can't tell you whether  17 I've heard it or not, so I can't tell you at  18 this moment whether I've ever heard that.  19 Q. You know what it means?  20 MS. JOHNSTON: Object to the  21 form.  22 THE WITNESS: I think it  23 depends on the situation. I would  24 need to know more about what you mean  25 by that question.</p>	<p style="text-align: right;">Page 180</p> <p>1 register for the industry-sponsored lunches,  2 or are they open for everyone?  3 MS. JOHNSTON: Object to the  4 form.  5 THE WITNESS: I don't know.  6 QUESTIONS BY MR. TRACEY:  7 Q. Okay. If you had to guess, how  8 many members of industry, ballpark, would you  9 say show up at the annual meeting?  10 MS. JOHNSTON: Object to the  11 form.  12 And I don't think Mr. Tracey  13 wants you to guess, Dr. D'Alton.  14 THE WITNESS: I really don't  15 know that number.  16 QUESTIONS BY MR. TRACEY:  17 Q. Okay. Flip over to page 17 --  18 sorry, yes, 17.  19 This is a list of institutions  20 and corporations that have donated money.  21 Do you recall seeing pages like  22 this in this material?  23 A. Let me just get there,  24 Mr. Tracey.  25 Q. Institutions and corporations,</p>
<p style="text-align: right;">Page 179</p> <p>1 QUESTIONS BY MR. TRACEY:  2 Q. Well, in the context of funding  3 of pharmaceutical trials, do you know what  4 the term "sponsorship bias" means?  5 MS. JOHNSTON: Object to the  6 form. Asked and answered.  7 THE WITNESS: I don't believe  8 I've ever heard of that with relation  9 to sponsorship bias. I really don't  10 know -- I really don't know what it  11 actually means.  12 QUESTIONS BY MR. TRACEY:  13 Q. Okay. So, and then we see that  14 the two -- there's a dinner sponsored -- a  15 dinner symposium sponsored on Tuesday evening  16 by Illumina, and then there are two different  17 industry learning lunches on Thursday and  18 Friday.  19 Do you see that?  20 MS. JOHNSTON: Object to the  21 form.  22 THE WITNESS: That's what it  23 states here, yes.  24 QUESTIONS BY MR. TRACEY:  25 Q. Do you know, do you have to</p>	<p style="text-align: right;">Page 181</p> <p>1 dead center of the page, second column,  2 starting with "100,000 or more."  3 AMAG Pharmaceuticals, which I  4 think is now Covis Pharmaceuticals.  5 A. This certainly refreshes my  6 memory. I certainly have seen this before.  7 Q. And these are -- these are  8 donors to the -- to the MFM foundation,  9 right?  10 MS. JOHNSTON: Object to the  11 form.  12 THE WITNESS: I don't know if  13 they're to the foundation or to the  14 society. I need to look that up. Oh,  15 foundation donors, you're correct.  16 Page 14. Okay.  17 QUESTIONS BY MR. TRACEY:  18 Q. Yep.  19 And so then we see the next one  20 after the pharmaceutical company -- by the  21 way, are you familiar with them?  22 A. AMAG?  23 Q. Yes.  24 A. Yes, I am.  25 Q. Okay. Do you know people at</p>

<p style="text-align: right;">Page 182</p> <p>1 AMAG?</p> <p>2 A. It no longer exists, so I don't</p> <p>3 know anyone there.</p> <p>4 Q. Well, they bought -- they were</p> <p>5 bought by Covis, right?</p> <p>6 A. I --</p> <p>7 MS. JOHNSTON: Object to the</p> <p>8 form.</p> <p>9 THE WITNESS: I don't remember</p> <p>10 who they were bought by. I don't know</p> <p>11 them in their current form.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. I see. Okay.</p> <p>14 And then we -- skip down to</p> <p>15 \$15,000, there's the Queenan Foundation and</p> <p>16 Sage Therapeutics, right?</p> <p>17 A. Yes.</p> <p>18 Q. Philips Healthcare is a \$7,500</p> <p>19 donor down there?</p> <p>20 A. I'm just trying to find that.</p> <p>21 Yes, I see that.</p> <p>22 Q. And then under the \$5,000</p> <p>23 level, there's an anonymous foundation,</p> <p>24 Beth Israel, and then you have a whole host</p> <p>25 of companies at the top of the next page.</p>	<p style="text-align: right;">Page 184</p> <p>1 page, because then we've got a bunch of logos</p> <p>2 of companies because there's something called</p> <p>3 the Foundation for SMFM Corporate Council</p> <p>4 Program, correct?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: That's correct.</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. And then we see the actual</p> <p>10 logos of some of the companies that belong to</p> <p>11 the corporate council program, right?</p> <p>12 MS. JOHNSTON: Object to the</p> <p>13 form.</p> <p>14 THE WITNESS: That is correct.</p> <p>15 QUESTIONS BY MR. TRACEY:</p> <p>16 Q. For example, we see Abbott</p> <p>17 Nutrition, we see AMAG Pharmaceuticals again.</p> <p>18 We see, in the middle there, Ferring</p> <p>19 Pharmaceuticals, right?</p> <p>20 A. Yes.</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 QUESTIONS BY MR. TRACEY:</p> <p>24 Q. General Electric's a name</p> <p>25 probably everybody knows, right?</p>
<p style="text-align: right;">Page 183</p> <p>1 You have Hologic, Integrated</p> <p>2 Genetics, Sema4, Sera Prognostics and Trice</p> <p>3 Imaging.</p> <p>4 Are you familiar with those</p> <p>5 companies?</p> <p>6 MS. JOHNSTON: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: I'm familiar with</p> <p>9 some of them, yes.</p> <p>10 QUESTIONS BY MR. TRACEY:</p> <p>11 Q. Okay.</p> <p>12 A. Not all of them.</p> <p>13 Q. Do you know some people at</p> <p>14 those companies or did you at the time?</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: Quite honestly, I</p> <p>18 don't know if I've -- if I've -- if I</p> <p>19 knew people at the time. The -- I</p> <p>20 find that the people at the companies</p> <p>21 change a lot.</p> <p>22 So I just -- I just don't know</p> <p>23 as I sit here today.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. Okay. Flip over to the next</p>	<p style="text-align: right;">Page 185</p> <p>1 MS. JOHNSTON: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: I don't know if</p> <p>4 everybody knows that, but many people</p> <p>5 in health care know it.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. And then if you flip over the</p> <p>8 next page, there was a Dan O'Keefe tribute</p> <p>9 event, and there was also sponsors for this</p> <p>10 in addition to what we've seen.</p> <p>11 True?</p> <p>12 MS. JOHNSTON: Object to the</p> <p>13 form.</p> <p>14 THE WITNESS: Just give me a</p> <p>15 minute to look through it. I'm sorry.</p> <p>16 That is correct.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. And so Dan was getting -- Dan</p> <p>19 O'Keefe was getting celebrated that night,</p> <p>20 right?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. And under the benefactors, we</p>

<p style="text-align: right;">Page 186</p> <p>1 see AMAG Pharmaceuticals again, don't we?</p> <p>2 A. Yes, I can find that now.</p> <p>3 Q. Yeah.</p> <p>4 And then we see you, Dr. Mary</p> <p>5 D'Alton, right?</p> <p>6 A. Yes.</p> <p>7 Q. And then we see eviCore</p> <p>8 Healthcare?</p> <p>9 A. Yes.</p> <p>10 Q. Peri --</p> <p>11 A. Yes.</p> <p>12 Q. You see PeriGen and Samsung?</p> <p>13 A. Yes.</p> <p>14 Q. They're \$10,000 contributors.</p> <p>15 And then we've got friends down</p> <p>16 below. We see Ferring Pharmaceuticals,</p> <p>17 Hologic and Integrated Genetics, the first</p> <p>18 three, don't we?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. Yeah. Yeah. So they're giving</p> <p>24 money for Dan's celebration, too, right?</p> <p>25 MS. JOHNSTON: Object to the</p>	<p style="text-align: right;">Page 188</p> <p>1 A. Okay. I'm sorry. It's hard</p> <p>2 for me to look on both the screen and the</p> <p>3 hard copy in front of me. I apologize. Just</p> <p>4 give me a moment. Thank you.</p> <p>5 Q. Sure. Let me know when you're</p> <p>6 ready.</p> <p>7 A. Okay. Yep.</p> <p>8 Q. It says, "Dan was personally</p> <p>9 responsible for spearheading the Society's</p> <p>10 advocacy efforts for the establishment of the</p> <p>11 leadership academy with Dr. Mike Foley and</p> <p>12 for conceiving the popular coding courses for</p> <p>13 the creation of the first-year fellows</p> <p>14 retreat and for connecting the Society with</p> <p>15 key industry leaders through the Foundation's</p> <p>16 corporate council program."</p> <p>17 It says, "He has raised the</p> <p>18 visibility of maternal-fetal medicine as a</p> <p>19 specialty and of the Society as an influencer</p> <p>20 of health insurers and policymakers."</p> <p>21 Is all of that true about Dan?</p> <p>22 MS. JOHNSTON: Object to the</p> <p>23 form.</p> <p>24 THE WITNESS: I don't know the</p> <p>25 details of all of this, but certainly</p>
<p style="text-align: right;">Page 187</p> <p>1 form.</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. Right?</p> <p>4 A. Well, I don't know exactly what</p> <p>5 the donation was for, how much of it was to</p> <p>6 the event or to the -- there was a course</p> <p>7 that was put on or a Dan O'Keefe fellowship.</p> <p>8 I don't remember -- it was -- it's not called</p> <p>9 a fellowship, but it's a Dan O'Keefe -- I</p> <p>10 think it's mentorship program. And how much</p> <p>11 was given for the event and to the mentorship</p> <p>12 program, I'm not aware of those details at</p> <p>13 this point.</p> <p>14 Q. Let's look there on the left</p> <p>15 hand. In the middle of the page it says,</p> <p>16 "Dan" -- did you know Dan, by the way, or do</p> <p>17 you know Dan?</p> <p>18 A. Yes, I do.</p> <p>19 Q. It says, "Dan was personally</p> <p>20 responsible," right there, "for</p> <p>21 spearheading" --</p> <p>22 A. Sorry, I can't find it. I --</p> <p>23 okay.</p> <p>24 Q. It's being highlighted as I</p> <p>25 read.</p>	<p style="text-align: right;">Page 189</p> <p>1 Dan was a excellent leader of --</p> <p>2 executive leader of the Society and</p> <p>3 was responsible for increasing the</p> <p>4 visibility of the Society and put many</p> <p>5 great programs into place. I can't</p> <p>6 comment on each one of them.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. Do you know whether he was</p> <p>9 responsible for connecting the Society with</p> <p>10 key industry leaders?</p> <p>11 MS. JOHNSTON: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: I mean, he may</p> <p>14 have been with some -- some key</p> <p>15 industry leaders. There are others</p> <p>16 that would be -- that would have --</p> <p>17 sorry -- introduced or made the</p> <p>18 Society aware of others. He certainly</p> <p>19 wasn't -- didn't make the contact with</p> <p>20 each individual industry leader.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. Okay. But what they say is</p> <p>23 true, right?</p> <p>24 MS. JOHNSTON: Object to the</p> <p>25 form.</p>

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1 THE WITNESS: I'm sorry. Let  
2 me see -- I just want to see what he  
3 said about -- I just want to see what  
4 it said about key industry leaders.  
5 Okay.  
6 QUESTIONS BY MR. TRACEY:  
7 Q. Does that make you  
8 uncomfortable to read that, Doctor?  
9 MS. JOHNSTON: Object to the  
10 form.  
11 THE WITNESS: No, it doesn't  
12 make me uncomfortable at all to read  
13 it. I just want to be precise in  
14 reading it so I can answer accurately  
15 for you, Mr. Tracey.  
16 I apologize, but just seeing it  
17 there and seeing it in front of me, I  
18 just want to make sure I'm answering  
19 it accurately.  
20 QUESTIONS BY MR. TRACEY:  
21 Q. Okay. Let me know when you're  
22 ready.  
23 A. I think that's reasonable.  
24 Q. Okay. And if we flip over on  
25 the next page, we see General Electric -- by

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1 the way, General Electric has a huge  
2 footprint in health care, don't they?  
3 MS. JOHNSTON: Object to the  
4 form.  
5 THE WITNESS: You know, I don't  
6 know the size of their footprint in  
7 health care. My own work with them in  
8 health care is mainly through imaging,  
9 and I don't know their actual  
10 footprint in health care.  
11 QUESTIONS BY MR. TRACEY:  
12 Q. You certainly are familiar with  
13 them, though, in the health care space?  
14 A. I'm definitely familiar with  
15 them in the imaging space as it pertains to  
16 health care.  
17 Q. And they are the sponsors of  
18 the VIP lounge.  
19 Do you see that?  
20 MS. JOHNSTON: Object to the  
21 form.  
22 THE WITNESS: I see that here  
23 now, yes.  
24 QUESTIONS BY MR. TRACEY:  
25 Q. Yeah.

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1 So that's the VIP lounge? Is  
2 that where, I guess, VIPs got to go?  
3 MS. JOHNSTON: Object to the  
4 form.  
5 THE WITNESS: I don't remember  
6 what the VIP lounge was, so -- I  
7 really can't remember what it was for.  
8 QUESTIONS BY MR. TRACEY:  
9 Q. Okay. Let's see if this sheds  
10 some light on it.  
11 It says, "VIP lounge sponsored  
12 by GE Healthcare, located in the Trinity II  
13 ballroom adjacent to registration. Open from  
14 7 a.m. to 5 p.m., Wednesday, the 31st,  
15 through Friday, February 2nd."  
16 It says, "Society and  
17 Foundation VIPs can enjoy a private gathering  
18 place to relax, connect, and network with  
19 access to comfortable seating, Wi-Fi,  
20 charging areas and light refreshments. Badge  
21 access to the lounge is available to current  
22 program committee members, past presidents of  
23 the Society, major contributors to the  
24 Foundation for SMFM and current SMFM and  
25 Foundation board members."

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1 Did I read that correctly?  
2 A. Yes, you did.  
3 Q. So what's going on is General  
4 Electric is sponsoring this VIP lounge where  
5 you can go network with members of -- or  
6 major contributors to the Foundation which  
7 some of whom we've just read about, right?  
8 MS. JOHNSTON: Object to the  
9 form.  
10 THE WITNESS: That's correct.  
11 QUESTIONS BY MR. TRACEY:  
12 Q. And you, you're a past  
13 president, so you're available -- you're  
14 allowed to go to the VIP lounge, right?  
15 MS. JOHNSTON: Object to the  
16 form.  
17 THE WITNESS: I'm allowed to  
18 go. I probably spent about five  
19 minutes there.  
20 QUESTIONS BY MR. TRACEY:  
21 Q. Okay. Well, look, I'm not --  
22 don't be defensive.  
23 A. No. I don't mean to be  
24 defensive. That's why I couldn't answer your  
25 question about what the VIP lounge was, and I

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1 just recall it now because I honestly didn't  
 2 have time to go there.  
 3 Q. I see.  
 4 And so you had to have badge  
 5 access to get in, right? That's what it  
 6 says.  
 7 MS. JOHNSTON: Object to the  
 8 form.  
 9 THE WITNESS: It says that  
 10 here, that's correct.  
 11 QUESTIONS BY MR. TRACEY:  
 12 Q. Yeah. There was security; not  
 13 anybody could go?  
 14 MS. JOHNSTON: Object to the  
 15 form.  
 16 THE WITNESS: I don't recall  
 17 any security there, but, you know,  
 18 putting a badge doesn't mean there's  
 19 security, in my view. Security means  
 20 having a security officer.  
 21 I don't recall ever having a  
 22 security officer there.  
 23 QUESTIONS BY MR. TRACEY:  
 24 Q. Okay. So you got current --  
 25 program committee members. What does that

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1 mean?  
 2 A. The program committee members  
 3 is a scientific program committee members,  
 4 and those would be the members that are  
 5 responsible for putting the program of the  
 6 Society together.  
 7 Q. Okay. So you got the people  
 8 responsible for the Society program, past  
 9 presidents of the Society, major contributors  
 10 to the Foundation, all get to network in the  
 11 VIP lounge sponsored by GE?  
 12 A. Well, I would say they all have  
 13 the potential to network. How many of them  
 14 get to network I think would depend on the  
 15 time available that they have and their own  
 16 personal preferences.  
 17 Q. Yeah. No. That's what I said,  
 18 they get to do it. Whether they choose to do  
 19 it, we don't know, right?  
 20 MS. JOHNSTON: Object to the  
 21 form.  
 22 THE WITNESS: I didn't quite  
 23 get the subtlety there, Mr. Tracey, so  
 24 thank you.  
 25

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1 QUESTIONS BY MR. TRACEY:  
 2 Q. You're welcome.  
 3 If we could turn to page 40,  
 4 we'll see "Luncheon Roundtables" and an  
 5 advertisement for industry-sponsored lunches  
 6 at the bottom.  
 7 A. I'm just trying to get there.  
 8 One second.  
 9 Q. Yeah, yeah. No rush.  
 10 A. Okay. Thank you.  
 11 Q. So there we have an  
 12 advertisement for lunches you can go to and  
 13 what's being presented by the industry  
 14 sponsors, right?  
 15 MS. JOHNSTON: Object to the  
 16 form.  
 17 THE WITNESS: I'm just reading  
 18 it here.  
 19 QUESTIONS BY MR. TRACEY:  
 20 Q. Let's read it together.  
 21 It says, "These independent  
 22 presentations are not part of the official  
 23 program as planned by the SMFM Program  
 24 Committee. Lunch is provided, and there is  
 25 no cost to attend, but attendees must be

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1 registered."  
 2 Did I read that correctly?  
 3 A. You did.  
 4 Q. Now, these are companies,  
 5 Sage Therapeutics and Natera, that have  
 6 products that they want to sell, right?  
 7 MS. JOHNSTON: Object to the  
 8 form.  
 9 THE WITNESS: Certainly they  
 10 may have.  
 11 QUESTIONS BY MR. TRACEY:  
 12 Q. Well, these are for-profit  
 13 companies, right?  
 14 MS. JOHNSTON: Object to the  
 15 form.  
 16 THE WITNESS: I presume they  
 17 are, yes.  
 18 QUESTIONS BY MR. TRACEY:  
 19 Q. And if we flip over to page 42,  
 20 you'll see some "commercially supported  
 21 events and sponsorships," and there's a  
 22 product theatre.  
 23 Do you see the product theatre  
 24 is a commercially supported events and  
 25 sponsorship?

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1 A. I do.

2 Q. And then you can just go

3 down -- you've got Samsung sponsoring one.

4 PartoSure is sponsoring one. Illumina, there

5 they are sponsoring the opening reception.

6 AMAG has got a charging lounge that they're

7 sponsoring.

8 Do you see all that?

9 MS. JOHNSTON: Object to the

10 form.

11 THE WITNESS: I do -- I do see

12 all of that, yes.

13 QUESTIONS BY MR. TRACEY:

14 Q. And let's turn to the

15 exhibitors on page 44, because from page 44

16 to I think 55 or so or 56, we have pages of

17 exhibitors. And here the Society is

18 extending "sincere thanks and appreciation to

19 the following companies and organizations for

20 their participation in the Pregnancy Meetings

21 Industry Exhibits. The following" --

22 A. Sorry, I can't see where you

23 are reading. I apologize.

24 Q. Yeah, top of the page.

25 A. Oh, thank you.

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1 Q. "The following are identified

2 as supporting and taking an active interest

3 in the activities of the Society."

4 That's an introduction to the

5 exhibitors for the attendees at the meeting,

6 isn't it?

7 MS. JOHNSTON: Object to the

8 form.

9 THE WITNESS: Well, I think

10 it's -- I don't read it as an

11 introduction. It could be, but it's

12 more expressing their gratitude for

13 their participation.

14 QUESTIONS BY MR. TRACEY:

15 Q. Gratitude, we're all in this

16 together, right?

17 MS. JOHNSTON: Object to the

18 form.

19 THE WITNESS: I don't think it

20 says that. It says their gratitude

21 for participation.

22 QUESTIONS BY MR. TRACEY:

23 Q. And taking an active interest

24 in our activities, right?

25 MS. JOHNSTON: Object to the

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1 form.

2 THE WITNESS: Yes.

3 QUESTIONS BY MR. TRACEY:

4 Q. And can you just scroll down?

5 You see the annual -- and whoever -- this is

6 AMAG again. They've got themselves a boxed

7 reference here, right? It's shaded and boxed

8 so it stands out, right?

9 MS. JOHNSTON: Object to the

10 form.

11 THE WITNESS: To my eye, it

12 doesn't look like it stands out, but

13 certainly it's in a -- it's -- I agree

14 that it's in a box.

15 QUESTIONS BY MR. TRACEY:

16 Q. But it's shaded a different

17 color than the rest of them, right?

18 MS. JOHNSTON: Object to the

19 form.

20 THE WITNESS: It is, yes.

21 QUESTIONS BY MR. TRACEY:

22 Q. So they direct you to booth 421

23 if you want to talk to those folks, right?

24 MS. JOHNSTON: Object to the

25 form.

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1 THE WITNESS: It shows where

2 they are located, yes.

3 QUESTIONS BY MR. TRACEY:

4 Q. And flip over two pages to 46,

5 and we have, again, shaded and box -- we have

6 two corporations that are now identified as

7 corporate council members.

8 Do you see that?

9 A. Sorry, where -- okay. Okay.

10 Q. Booth 109, they're not just

11 sponsors; they're also corporate council

12 members, right?

13 MS. JOHNSTON: Object to the

14 form.

15 THE WITNESS: Yes.

16 QUESTIONS BY MR. TRACEY:

17 Q. Yeah.

18 And they say that they're the

19 largest manufacturer exclusively focused on

20 L&D. That's what Clinical Innovations has to

21 say about themselves, right?

22 A. I'm sorry, I'm not able to keep

23 up with you here. Just show me where that

24 is. Thank you.

25 Q. Do you see it now?

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1 A. I do.

2 Q. "Clinical Innovations has

3 become the largest health care manufacturer

4 exclusively focused on L&D."

5 A. That's what's stated here.

6 Q. And then they list off all

7 their products that they're market leaders in

8 below that.

9 Do you see that?

10 A. I'm trying to read it along

11 with you here.

12 Q. And they say "if you want to

13 see us, come see us at booth 109."

14 Right?

15 A. It just states 10 -- booth 109.

16 It shows where the location is.

17 Q. Yeah. Over to the right, you

18 see another, CombiMatrix, booth 427.

19 Do you know those folks?

20 A. No, I don't.

21 Q. Okay. If you scroll up a bit,

22 Ray, it's another boxed one. There you go.

23 You don't know those folks in

24 booth 427?

25 MS. JOHNSTON: Object to the

Page 203

1 form.

2 THE WITNESS: No, I don't know

3 CombiMatrix, no.

4 QUESTIONS BY MR. TRACEY:

5 Q. All right. Flip over to the

6 next page. We got another company called

7 Counsyl. They're in booth 139.

8 Do you see them?

9 A. Yes, I see that.

10 Q. Now, they're shaded but not

11 boxed, right?

12 MS. JOHNSTON: Object to the

13 form.

14 THE WITNESS: Yes.

15 QUESTIONS BY MR. TRACEY:

16 Q. But down to the right, you see

17 Ferring Pharmaceuticals. They got shaded and

18 boxed, didn't they?

19 A. That's what it shows on this

20 page, yes.

21 Q. And they're in booth 221?

22 A. That's what it states here,

23 yes.

24 Q. Do you know any of the folks at

25 Ferring?

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1 A. I don't know -- not to my

2 knowledge. Have I ever met with one of them

3 or been introduced? I can't tell you that at

4 this point, but I could not sit here and tell

5 you any one person who's at Ferring.

6 Q. All right. Flip over to the

7 next page, we'll see -- dead center, we see

8 GE's got a booth, right? See that?

9 A. Yes.

10 Q. Flip over two pages, we got

11 three corporations on this page with booths.

12 Foundation --

13 A. I'm sorry, I'm trying to get

14 there. I apologize. Okay. Got it. Yeah, I

15 have it.

16 Q. And then over to the right, we

17 got Lupin Pharmaceuticals, booth 108?

18 A. Yes.

19 MS. JOHNSTON: Object to the

20 form.

21 QUESTIONS BY MR. TRACEY:

22 Q. And then down below, we've got

23 integratedgenetics.com, booth 115, don't we?

24 MS. JOHNSTON: Object to the

25 form.

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1 THE WITNESS: I'm just finding

2 it here. Yes. I see that.

3 QUESTIONS BY MR. TRACEY:

4 Q. And flip over to the next page,

5 we've got Nanosonics in booth 316.

6 MS. JOHNSTON: Object to the

7 form.

8 THE WITNESS: Yes.

9 MS. JOHNSTON: Hey, Sean, just

10 to get a sense of whether you're going

11 to read this entire 60-page document

12 and ask her to agree that it says what

13 it says. I think we're looking to

14 take a lunch break soon, so...

15 MR. TRACEY: I'm almost done.

16 MS. JOHNSTON: Okay. Well, I

17 think we've read the whole thing.

18 QUESTIONS BY MR. TRACEY:

19 Q. Yeah, I want you -- Doctor,

20 just flip through it, and you'll see that on

21 every page, there are multiple corporations

22 and pharmaceutical companies that have

23 purchased booths at your annual meeting.

24 Do you see that?

25 MS. JOHNSTON: Object to the

<p style="text-align: right;">Page 206</p> <p>1 form.</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. Just keep flipping through.</p> <p>4 A. Yes, I think I've finished.</p> <p>5 I'm on page -- I can't even see the name of</p> <p>6 this page, the number of this page, 56. I'm</p> <p>7 at 56.</p> <p>8 Q. Okay. Do you know anybody at</p> <p>9 Johnson &amp; Johnson or Janssen or McNeil?</p> <p>10 MS. JOHNSTON: Object to the</p> <p>11 form.</p> <p>12 THE WITNESS: Not that anyone</p> <p>13 comes to mind, no.</p> <p>14 MR. TRACEY: Okay. Let's --</p> <p>15 we're going to take a lunch break now?</p> <p>16 MS. JOHNSTON: Yeah. I think</p> <p>17 so. I think --</p> <p>18 MR. TRACEY: Tell me --</p> <p>19 MS. JOHNSTON: We've got some</p> <p>20 food here. So can we take 30?</p> <p>21 MR. TRACEY: Yeah, 30 -- why</p> <p>22 don't we say come back at 12:15 -- I</p> <p>23 guess 1:15 your time.</p> <p>24 MS. JOHNSTON: Yeah, that</p> <p>25 sounds good.</p>	<p style="text-align: right;">Page 208</p> <p>1 disclosed it to any of my residents or</p> <p>2 fellows.</p> <p>3 QUESTIONS BY MR. TRACEY:</p> <p>4 Q. Why not?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: I don't really</p> <p>8 see any indication for me to do that.</p> <p>9 I am -- I have not had occasion to</p> <p>10 talk to -- to give a lecture to</p> <p>11 residents about acetaminophen in</p> <p>12 pregnancy, and if I did, I would</p> <p>13 probably mention it and disclose that</p> <p>14 I was a consultant.</p> <p>15 QUESTIONS BY MR. TRACEY:</p> <p>16 Q. Okay. Would that same be true</p> <p>17 if you talked to a patient about</p> <p>18 acetaminophen in pregnancy?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: If a patient</p> <p>22 asked me about acetaminophen in</p> <p>23 pregnancy, yes, I would say that I --</p> <p>24 my -- you know, give them my opinions.</p> <p>25 And I would say, in fact, I've</p>
<p style="text-align: right;">Page 207</p> <p>1 MR. TRACEY: Okay. All right.</p> <p>2 Thanks, guys.</p> <p>3 VIDEOGRAPHER: The time right</p> <p>4 now is 12:41 p.m. We're off the</p> <p>5 record.</p> <p>6 (Off the record at 12:41 p.m.)</p> <p>7 VIDEOGRAPHER: The time right</p> <p>8 now is 1:24 p.m. We are back on the</p> <p>9 record.</p> <p>10 QUESTIONS BY MR. TRACEY:</p> <p>11 Q. Hi, Dr. D'Alton. Are you ready</p> <p>12 to continue?</p> <p>13 A. Yes, I am. Thank you.</p> <p>14 Q. All right. Do you disclose to</p> <p>15 patients that you're a consultant for Johnson</p> <p>16 &amp; Johnson?</p> <p>17 MS. JOHNSTON: Object to the</p> <p>18 form.</p> <p>19 THE WITNESS: No, I have not</p> <p>20 disclosed that to patients.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. Do you disclose it to any of</p> <p>23 your residents or fellows?</p> <p>24 MS. JOHNSTON: Same objection.</p> <p>25 THE WITNESS: No, I have not</p>	<p style="text-align: right;">Page 209</p> <p>1 been asked to give my opinions about</p> <p>2 this on the record and testify on this</p> <p>3 issue.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. Well, that's a little different</p> <p>6 than disclosing that they're paying \$600 an</p> <p>7 hour, right?</p> <p>8 MS. JOHNSTON: Object to the</p> <p>9 form.</p> <p>10 THE WITNESS: Yeah. I -- I'm</p> <p>11 not sure I've ever done that to a</p> <p>12 patient, disclose that I do</p> <p>13 consulting. Certainly if they asked</p> <p>14 me how much I was getting paid, I</p> <p>15 would -- I would be transparent about</p> <p>16 that.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. When you were having the</p> <p>19 conversations you talked about in 2021 and</p> <p>20 2022 with patients or residents or fellows,</p> <p>21 did you ever give any patients the consensus</p> <p>22 statement?</p> <p>23 MS. JOHNSTON: Object to the</p> <p>24 form.</p> <p>25 THE WITNESS: No, I did not.</p>

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1 QUESTIONS BY MR. TRACEY:

2 Q. Did you give them the ACOG

3 statement?

4 A. No, I did not.

5 MS. JOHNSTON: Object to the

6 form.

7 (D'Alton Exhibit 938B marked

8 for identification.)

9 QUESTIONS BY MR. TRACEY:

10 Q. Okay. Okay. I'm going to hand

11 you or somebody is going to hand you

12 Exhibit 30 -- 938B. This is a graph that I

13 got from the Society for Maternal-Fetal

14 Medicine website, their annual report.

15 2017 is the --

16 A. Sorry --

17 Q. The year that the --

18 A. Sorry, I don't -- I don't have

19 it yet.

20 RAY MOORE: We don't have that

21 one printed. That was an addition.

22 MS. JOHNSTON: We don't have a

23 copy of this one.

24 THE WITNESS: Oh, we don't have

25 it?

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1 MS. JOHNSTON: And, Sean, I got

2 to tell you, it's very small --

3 THE WITNESS: It's tiny.

4 MS. JOHNSTON: -- on the

5 screen.

6 MR. TRACEY: There we go.

7 MS. JOHNSTON: Well, yeah. Is

8 it possible to -- I mean, we can give

9 you a paralegal or someone to e-mail

10 that to, but it's -- we can't take it

11 all in at once.

12 MR. TRACEY: Well, there's only

13 one tiny section of it we're going to

14 talk about.

15 MS. JOHNSTON: Well, I think --

16 is this -- is this an exhibit share,

17 or is this something that -- okay.

18 Before you ask questions about

19 it, I would like to at least be able

20 to take a look at it, Sean.

21 MR. TRACEY: Okay. Go ahead.

22 THE WITNESS: Do you mind if I

23 pull the computer closer? It's very

24 tiny. It's hard for me to see.

25 MS. JOHNSTON: Mary, I think

Page 212

1 we're going to get a copy of this

2 printed so that --

3 RAY MOORE: Can we go off the

4 record?

5 VIDEOGRAPHER: The time is

6 1:28 p.m.

7 (Off the record at 1:28 p.m.)

8 VIDEOGRAPHER: The time right

9 now is 1:38 p.m. We're back on the

10 record.

11 QUESTIONS BY MR. TRACEY:

12 Q. Okay. Doctor, you have 938B in

13 front of you now?

14 A. Yes, I do.

15 Q. And this is from the annual

16 report of the Society for Maternal-Fetal

17 Medicine from 2017.

18 Do you see that at the top?

19 A. Yes, I do.

20 Q. And 2017 was the year that the

21 Society for Maternal-Fetal Medicine responded

22 to -- or put out their position paper on

23 Tylenol in pregnancy, right?

24 MS. JOHNSTON: Object to the

25 form.

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1 THE WITNESS: Yes.

2 QUESTIONS BY MR. TRACEY:

3 Q. And in that year, if you look

4 at the source of the revenue for the Society

5 for Maternal-Fetal Medicine, there you see it

6 says 2017 revenue, \$5,093,238?

7 A. Yes.

8 Q. And then you see where it's got

9 industry is -- industry support is 26 percent

10 of the annual revenue.

11 Do you see that?

12 A. Just let me look here. I can't

13 find that here.

14 MS. JOHNSTON: Sean, I'm just

15 going to point to her.

16 THE WITNESS: Okay. Got it.

17 Thank you.

18 QUESTIONS BY MR. TRACEY:

19 Q. Industry support? One, two,

20 three lines down, boxes down?

21 A. Yes, I see that.

22 Q. And I'm color blind. I don't

23 know what color that is, but I know it

24 matches up with the 26 percent in the pie

25 chart to the left.

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1 A. Yes.

2 Q. So in 2017, 26 percent of the

3 Society's revenue came from industry.

4 MS. JOHNSTON: Object to the

5 form.

6 QUESTIONS BY MR. TRACEY:

7 Q. Right?

8 A. That's what it states here,

9 yes.

10 Q. That is literally the

11 definition of a conflict of interest, isn't

12 it?

13 MS. JOHNSTON: Object to the

14 form.

15 THE WITNESS: In my view, it's

16 not the definition of a conflict of

17 interest. It depends on what it's

18 related to. It has provided support

19 for their annual meeting, but it

20 doesn't say anything about what else

21 it has provided income for.

22 QUESTIONS BY MR. TRACEY:

23 Q. Well, it's just under the

24 revenue generally, right?

25 A. Yes, and they reported it here.

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1 They reported what exactly they're getting

2 from industry.

3 Q. Yes. Over, like, a million

4 250, a little over a million 250 in 2017 in

5 revenue from industry, right?

6 MS. JOHNSTON: Object to the

7 form.

8 THE WITNESS: That's what the

9 Society reports here, yes.

10 QUESTIONS BY MR. TRACEY:

11 Q. Okay. And that's the very year

12 that the Society weighed in on the

13 acetaminophen/neurodevelopmental disorder

14 controversy, correct?

15 MS. JOHNSTON: Object to the

16 form.

17 THE WITNESS: The publications

18 committee of the Society weighed in on

19 that, yes.

20 QUESTIONS BY MR. TRACEY:

21 Q. Yes. And we're going to look

22 at it in just a second.

23 Okay. And then can you please

24 bring up, Ray, Exhibit 930A?

25 (D'Alton Exhibit 930A marked

Page 216

1 for identification.)

2 QUESTIONS BY MR. TRACEY:

3 Q. And I hope you have a copy of

4 this.

5 This is -- this is going to be

6 very brief. This is the 43rd Annual

7 Pregnancy Meeting of the Society which took

8 place this year in San Francisco.

9 Did you attend that meeting?

10 A. Yes, I did.

11 Q. And this is a -- this is a

12 booth number 815 that Janssen and Johnson &

13 Johnson and Janssen Biotech apparently rented

14 or leased at the meeting.

15 Do you see that?

16 MS. JOHNSTON: Object to the

17 form.

18 THE WITNESS: Just let me look

19 at it here. Yes.

20 MR. TRACEY: I don't know if

21 you could make it any bigger, Ray

22 that -- yeah. Thank you.

23 QUESTIONS BY MR. TRACEY:

24 Q. It says, "At Janssen, we're

25 creating a future where disease is a thing of

Page 217

1 past. We're the pharmaceutical companies of

2 Johnson & Johnson, working for patients

3 everywhere, fighting sickness with science,

4 improving access with ingenuity and healing

5 hopelessness."

6 And then it's got their

7 address, right?

8 A. Yes.

9 MS. JOHNSTON: And I'll just

10 object that it looks like there's some

11 language that was potentially left

12 off. So I'm not sure this is a

13 complete document, but you can ask her

14 questions.

15 MR. TRACEY: Yeah, that's -- I

16 don't know why it didn't print. I

17 don't remember what it was.

18 QUESTIONS BY MR. TRACEY:

19 Q. Anyway, and then they had

20 booth 815 this year, right?

21 MS. JOHNSTON: Object to the

22 form.

23 THE WITNESS: That's what it

24 states, yes.

25

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1 QUESTIONS BY MR. TRACEY:

2 Q. When did you get hired by the

3 lawyers for Johnson & Johnson?

4 MS. JOHNSTON: Object to the

5 form.

6 THE WITNESS: I believe it was

7 sometime in March of this year.

8 QUESTIONS BY MR. TRACEY:

9 Q. March of this year. Just after

10 this meeting?

11 A. Yes, it was after this meeting.

12 Q. How did you get hired?

13 MS. JOHNSTON: Object to the

14 form.

15 THE WITNESS: I got a call from

16 one of the attorneys. Quite honestly,

17 at this date, I don't remember which

18 attorney called me.

19 QUESTIONS BY MR. TRACEY:

20 Q. How did they get your name?

21 MS. JOHNSTON: Object to the

22 form.

23 THE WITNESS: I don't --

24 MS. JOHNSTON: Calls for

25 speculation.

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1 And, Mary, I'm sure Mr. Tracey

2 would tell you this, but he doesn't

3 want to know anything that may have

4 been discussed with attorneys.

5 MR. TRACEY: No. No. I'm just

6 curious if you know how they found

7 you.

8 THE WITNESS: I don't know how

9 they got my name, no.

10 QUESTIONS BY MR. TRACEY:

11 Q. Okay. Do you remember meeting

12 with anybody from Janssen or Johnson &

13 Johnson at the annual meeting in February?

14 A. I can tell you I did not meet

15 with anyone at -- from Johnson & Johnson or

16 with any other pharmaceutical company or

17 device company at the meeting.

18 (D'Alton Exhibit 938A marked

19 for identification.)

20 QUESTIONS BY MR. TRACEY:

21 Q. Okay. Okay. Let's look at

22 Exhibit 938A, which is the Society statement

23 that was put out in 2017.

24 Now --

25 A. Can you just wait a minute

Page 220

1 until I get a copy, please? It hasn't been

2 brought to me yet.

3 Thank you.

4 Q. Let me know when you're ready.

5 Are you ready, Doctor?

6 A. Yes.

7 Q. This statement is in your

8 report almost in its entirety, isn't it?

9 A. I don't recall that it's in its

10 entirety in my report, but certainly some

11 portions of this report are in my -- or

12 sorry, of this statement are in my report.

13 Q. Did you rely on this statement

14 in forming your opinions?

15 A. I certainly used it in coming

16 to my opinions, and I agreed with the

17 statement in coming to my opinions, but I

18 didn't rely on it. I made my own -- I made

19 my own determination about my opinions.

20 Q. Who are the authors of this?

21 A. It's -- it doesn't state who

22 the authors are, and it says it's from the

23 publications committee of the Society.

24 Q. Why doesn't it have the -- why

25 don't we have the identity of the authors?

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1 MS. JOHNSTON: Object to the

2 form.

3 THE WITNESS: I can't answer

4 that. I have not been on the

5 publications committee for the Society

6 for Maternal-Fetal Medicine.

7 QUESTIONS BY MR. TRACEY:

8 Q. And this was published, it

9 says, in March of 2017?

10 A. That's correct.

11 Q. Since that time, how many human

12 epidemiology studies have been published that

13 looked at the issue of acetaminophen and

14 adverse neurodevelopmental outcomes?

15 MS. JOHNSTON: Object to the

16 form.

17 THE WITNESS: I can't tell you

18 the number that have been published,

19 but a number of epidemiology studies

20 have been published that I alluded to

21 in my report that has looked at the

22 association between prenatal use of

23 acetaminophen and ADHD and ASD.

24 QUESTIONS BY MR. TRACEY:

25 Q. No doubt, ma'am.

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1 Do you recall reading a study  
2 called Ji in 2020 out of the Boston Birth  
3 Cohort?  
4 A. I certainly recall reading it.  
5 When I read it, I can't recall for you at  
6 this point.  
7 Q. Do you recall that that was  
8 published after this statement from the  
9 Society?  
10 A. Yes, it was published. It was  
11 2020, so clearly it was after the statement  
12 from the Society.  
13 Q. And then the Baker 2020 paper  
14 also published, obviously, after the Society  
15 statement. You certainly know that paper?  
16 A. Yes, I know that paper. That  
17 was also published after the opinions of the  
18 Society.  
19 Q. And you also know about the  
20 Alemany meta-analysis published in 2021,  
21 right?  
22 A. I've -- I don't remember all of  
23 the details of the meta-analysis at this  
24 point, but I do know that it was published in  
25 2021.

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1 Q. And both Ji and Baker use  
2 biomarkers to determine acetaminophen  
3 exposure, didn't they?  
4 MS. JOHNSTON: Object to the  
5 form.  
6 THE WITNESS: Yes, they used --  
7 Ji used biomarkers and in cord blood  
8 and in -- and cord blood, and Baker  
9 used acetaminophen levels in meconium.  
10 QUESTIONS BY MR. TRACEY:  
11 Q. And do you know, has the  
12 Society, in the six and a half years since  
13 they issued this statement, updated any of  
14 their positions that you know of?  
15 A. They have not updated their  
16 positions, no.  
17 Q. Okay. Ma'am, do you, when you  
18 look at studies, look at them objectively?  
19 MS. JOHNSTON: Object to the  
20 form.  
21 THE WITNESS: I try and do  
22 that, yes.  
23 QUESTIONS BY MR. TRACEY:  
24 Q. Do you look at both the  
25 strengths and the weaknesses or limitations

Page 224

1 of studies?  
2 A. I try to do that, yes.  
3 Q. And that's the right thing to  
4 do if you're going to be honest about what  
5 the data says; it's to look at the strengths  
6 and the limitations, correct?  
7 A. That's some of the -- that's  
8 some of the items that you would look at,  
9 yes.  
10 Q. That is, you wouldn't want to  
11 focus only on the weaknesses or limitations  
12 and nor would you want to focus only on the  
13 strengths of the study, would you?  
14 MS. JOHNSTON: Object to the  
15 form.  
16 THE WITNESS: I think  
17 evaluating the whole study for respect  
18 to strengths and weaknesses and  
19 methodologic design and consistency  
20 with other studies and -- is important  
21 in reviewing an article.  
22 QUESTIONS BY MR. TRACEY:  
23 Q. Yeah.  
24 We don't want to decide what  
25 the answer is and then look at the evidence

Page 225

1 to support what we want. That's not what you  
2 do. That's not scientific, is it?  
3 MS. JOHNSTON: Object to the  
4 form.  
5 THE WITNESS: Clearly you don't  
6 want to look at the answer you want.  
7 You want to evaluate the paper for  
8 what it is and inform you as to --  
9 inform you as to your opinion.  
10 QUESTIONS BY MR. TRACEY:  
11 Q. And science should be the  
12 relentless pursuit of the truth, right?  
13 MS. JOHNSTON: Object to the  
14 form.  
15 THE WITNESS: I think that's a  
16 very good goal in -- for scientific  
17 investigation.  
18 QUESTIONS BY MR. TRACEY:  
19 Q. It should be free of money  
20 changing hands or whether you're going to get  
21 funded next year or whether I'm going to get  
22 a donation for my foundation.  
23 It should be free of all of  
24 those considerations, shouldn't it, Doctor?  
25 MS. JOHNSTON: Object to the

Page 226

1 form.

2 THE WITNESS: Well, it's hard

3 to be free of all of those

4 considerations because we get funding

5 for clinical investigations from our

6 government agencies, and that's one of

7 the ways we measure the research, is

8 did it have NIH funding.

9 And so NIH funding is very much

10 at arm's length with respect to

11 clinical trials, and clinical trials

12 are designed by the investigators.

13 And in determining the role of

14 a pharmaceutical company in clinical

15 trials, one would want to see what was

16 the -- what was the funding and

17 whether there was editorial

18 independence and what relationship the

19 investigators had with the company.

20 QUESTIONS BY MR. TRACEY:

21 Q. Do you remember my question?

22 A. Yes. You asked me would --

23 could science be free from monies.

24 And to do appropriate clinical

25 trials, it requires funding. There is -- it

Page 227

1 is not possible to do a proper -- in general,

2 to do a very large clinical trial without

3 having the benefit of some funding to do it.

4 Q. Yeah, that's not really what I

5 asked.

6 What I asked was, when you're

7 reviewing evidence in a case, you should be

8 doing it in the relentless pursuit of the

9 truth, unencumbered by worries about

10 whether you're going to get funded by

11 industry next year for a study or whether

12 they're going to fund your foundation or

13 whether they're going to continue to

14 contribute to your revenue stream.

15 That was my question.

16 MS. JOHNSTON: If you're

17 reasking it, I object to the form,

18 again.

19 THE WITNESS: So there's a lot

20 in there. Can you just -- could I

21 just ask to have it read back?

22 There's a lot of parameters in that.

23 QUESTIONS BY MR. TRACEY:

24 Q. Let me do it one at a time.

25 A. Okay. Thank you.

Page 228

1 Q. When you're evaluating evidence

2 of whether a drug is harmful to a fetus, you

3 should do it without worrying or considering

4 whether your society is going to get funded

5 by industry next year, shouldn't you?

6 MS. JOHNSTON: Object to the

7 form.

8 THE WITNESS: Yes, definitely.

9 QUESTIONS BY MR. TRACEY:

10 Q. And you should do it free from

11 considerations of whether the -- whether

12 industry is going to fund your next study

13 that you want to do at your medical school?

14 MS. JOHNSTON: Same objection.

15 THE WITNESS: Yes, I would say

16 that's -- your future funding with

17 respect to this should not be a

18 consideration.

19 QUESTIONS BY MR. TRACEY:

20 Q. And you mentioned the NIH and

21 the federal government, but the federal

22 government is not a manufacturer of

23 pharmaceutical products, are they?

24 A. That's correct.

25 Q. They're not a for-profit

Page 229

1 enterprise, are they?

2 A. That's correct.

3 Q. All right. I want you to take

4 a look at this -- at Exhibit 938, and I want

5 you to tell me where -- whoever these authors

6 are, where they detailed the strengths of the

7 studies that they identified.

8 MS. JOHNSTON: Object to the

9 form.

10 THE WITNESS: Okay. If you

11 just give me a moment to quickly look

12 at this, that would be helpful.

13 QUESTIONS BY MR. TRACEY:

14 Q. Absolutely. It's one and a

15 half pages long. Take all the time you need

16 looking for a strengths section.

17 A. Okay.

18 Q. Any luck?

19 A. I'm just -- I'm not quite

20 finished, Mr. Tracey. I'm doing my best to

21 read quickly.

22 Q. Okay. No, I don't want to rush

23 you on this one.

24 A. Thank you.

25 Q. How are we doing?

Page 230

1 A. I -- I'm pretty close. I think  
 2 I have two more paragraphs.  
 3 Q. Okay.  
 4 A. I don't see strengths of the  
 5 individual studies reported here.  
 6 Q. Not one is mentioned, correct?  
 7 MS. JOHNSTON: Object to the  
 8 form.  
 9 THE WITNESS: That's correct.  
 10 The strengths of these studies are not  
 11 mentioned.  
 12 QUESTIONS BY MR. TRACEY:  
 13 Q. Does that seem odd to you?  
 14 MS. JOHNSTON: Object to the  
 15 form.  
 16 THE WITNESS: It's not really  
 17 odd because they're giving advice  
 18 about the existing data and a -- for  
 19 whatever reason, they felt it was  
 20 important to -- like in concurrence  
 21 with the FDA -- point out the  
 22 significant weaknesses that would  
 23 allow a causal connection between  
 24 maternal ingestion of acetaminophen,  
 25 maternal use of acetaminophen, and

Page 231

1 ADHD and ASD.  
 2 QUESTIONS BY MR. TRACEY:  
 3 Q. What does that have to do with  
 4 failing to identify the strengths in studies?  
 5 MS. JOHNSTON: Object to the  
 6 form.  
 7 THE WITNESS: Well, I think the  
 8 strengths of the studies in this  
 9 instance, the cohorts, were not  
 10 sufficient to answer this question.  
 11 QUESTIONS BY MR. TRACEY:  
 12 Q. Hmm.  
 13 A. And they point that out pretty  
 14 clearly.  
 15 Q. Well, let's look at the second  
 16 page. Let's actually look at their  
 17 conclusion.  
 18 In the last paragraph they say,  
 19 "Based on our evaluation of these studies, we  
 20 believe the weight of the evidence is  
 21 inconclusive regarding a possible causal  
 22 relationship."  
 23 Right?  
 24 We don't know, right?  
 25 MS. JOHNSTON: Object to the

Page 232

1 form.  
 2 THE WITNESS: It's -- that's  
 3 what they state here.  
 4 QUESTIONS BY MR. TRACEY:  
 5 Q. You didn't say that in your  
 6 report. You said acetaminophen has been  
 7 proven safe in your report, right?  
 8 MS. JOHNSTON: Object to the  
 9 form.  
 10 THE WITNESS: Well, that was my  
 11 opinion, and based on my review of the  
 12 literature and including this document  
 13 and the weight of the evidence in the  
 14 literature.  
 15 QUESTIONS BY MR. TRACEY:  
 16 Q. Can you name, Dr. D'Alton, a  
 17 single epidemiology study that exonerated  
 18 Tylenol in a study that looked at whether it  
 19 causes neurodevelopmental outcomes?  
 20 MS. JOHNSTON: Object to the  
 21 form.  
 22 QUESTIONS BY MR. TRACEY:  
 23 Q. A single study.  
 24 A. Well, there's many studies that  
 25 share that they can't come to a causal

Page 233

1 connection with respect to acetaminophen  
 2 and ADHD and ASD.  
 3 Q. But this was my question.  
 4 A. Uh-huh.  
 5 Q. Can you name a single  
 6 epidemiology study that looked at the  
 7 question of whether or not Tylenol causes  
 8 ADHD or ASD and found no association, a  
 9 single study?  
 10 MS. JOHNSTON: Object to the  
 11 form.  
 12 THE WITNESS: Well, certainly  
 13 Saunders from Canada has reported on  
 14 the lack of an association between  
 15 maternal use of acetaminophen and ASD  
 16 was a report in her study.  
 17 Similarly, Liew, in 2016,  
 18 reported on the association of  
 19 prenatal acetaminophen and ASD and  
 20 found that it was only -- it was only  
 21 associated with -- ASD with  
 22 hyperkinetic syndrome --  
 23 QUESTIONS BY MR. TRACEY:  
 24 Q. All right.  
 25 A. -- but was not associated with

Page 234

1 other types of ASD.  
 2 So certainly those are two  
 3 studies that came to mind.  
 4 And quite honestly, the Ji  
 5 studies on acetaminophen in pregnancy related  
 6 to cord blood have no information on when  
 7 the -- when the acetaminophen was taken or  
 8 why it was taken so they could not reach that  
 9 conclusion. They could only state that the  
 10 acetaminophen levels in cord blood was  
 11 associated without giving me, as a clinician,  
 12 any evidence of why the acetaminophen was  
 13 used, how long it was used for, and the  
 14 multiple confounders in the -- that they were  
 15 unable to address in the literature -- in  
 16 their cohort, excuse me, in the Boston Birth  
 17 Cohort.  
 18 Q. Okay. So you've mentioned  
 19 Saunders, Liew 2016 and the Ji study.  
 20 Those -- those all, you  
 21 believe, exonerate Tylenol?  
 22 MS. JOHNSTON: Object to the  
 23 form.  
 24 THE WITNESS: Well, you know,  
 25 I'm not saying I would use the word

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1 "exonerate." What I would say is that  
 2 there was no association. And Ji from  
 3 2019 did not report an association  
 4 between maternal plasma levels of  
 5 acetaminophen and ASD.  
 6 QUESTIONS BY MR. TRACEY:  
 7 Q. Okay. Any other studies?  
 8 A. I believe that's the weight of  
 9 the evidence in ASD.  
 10 Q. How many go the other  
 11 direction, Dr. D'Alton?  
 12 MS. JOHNSTON: Object to the  
 13 form.  
 14 THE WITNESS: Well, in ASD,  
 15 there's -- I'm not aware of any that  
 16 go the other direction. I've said  
 17 that -- I've given you my analysis of  
 18 Ji and -- sorry, of Liew from 2016,  
 19 and the Ji papers from '19 and '20,  
 20 and Saunders showing no association.  
 21 So the majority of the studies  
 22 with -- related to acetaminophen use  
 23 and ASD do not report an association.  
 24 QUESTIONS BY MR. TRACEY:  
 25 Q. What does the Alemany

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1 meta-analysis say about ASD and Tylenol?  
 2 A. I --  
 3 MS. JOHNSTON: Object to the  
 4 form.  
 5 THE WITNESS: I -- I'd have to  
 6 look at the Alemany meta-analysis,  
 7 but -- however, meta-analysis is only  
 8 as good as the data you put into it,  
 9 and it's not as good as the primary  
 10 review of the -- of the data.  
 11 So I can't recall at this  
 12 point. And I'd be happy to look it up  
 13 here, if you want me to comment  
 14 further on it.  
 15 QUESTIONS BY MR. TRACEY:  
 16 Q. Let's look at what the authors  
 17 said about the conflicts of interest in this  
 18 paper from the Society. I found this very  
 19 interesting.  
 20 They say, "All authors and  
 21 committee members have filed a conflict of  
 22 interest disclosure delineating personal,  
 23 professional or business interests that might  
 24 be perceived as a real or potential conflict  
 25 of interest in relation to this publication.

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1 Any conflicts have been resolved through a  
 2 process approved by the executive board. The  
 3 Society for Maternal-Fetal Medicine has  
 4 neither solicited nor accepted any commercial  
 5 involvement in the development of the content  
 6 of this publication."  
 7 Do you see that, ma'am?  
 8 A. Yes, I do.  
 9 Q. And as we talked about before,  
 10 we don't know who the authors or the  
 11 committee members are who wrote this paper,  
 12 do we?  
 13 MS. JOHNSTON: Object to the  
 14 form.  
 15 THE WITNESS: It doesn't state  
 16 that, but if there were any questions  
 17 related to the document, it states  
 18 here they should be referred to the  
 19 SMFM publications committee.  
 20 QUESTIONS BY MR. TRACEY:  
 21 Q. Why not disclose them for the  
 22 public to see, ma'am?  
 23 MS. JOHNSTON: Object to the  
 24 form.  
 25 THE WITNESS: I'm not

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1 exactly -- as I shared with you  
 2 earlier today, I have not been on the  
 3 SMFM publications committee, and I'm  
 4 not totally familiar with their  
 5 conflict of interest policy, or how it  
 6 is disclosed, but they certainly are  
 7 transparent about telling us about the  
 8 process here, as you pointed out on  
 9 the document here.

10 QUESTIONS BY MR. TRACEY:  
 11 Q. They're transparent about not  
 12 telling us who the authors are or whether  
 13 there are any conflicts with the authors?

14 MS. JOHNSTON: Object to the  
 15 form.

16 THE WITNESS: Well --

17 QUESTIONS BY MR. TRACEY:  
 18 Q. You think that's transparent?

19 A. Well, it says that all authors  
 20 and committee members have filed a conflict  
 21 of interest disclosure policy.

22 Q. Yes.

23 A. And that any conflicts were  
 24 resolved through a process approved by the  
 25 executive board.

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1 Q. Yes.  
 2 How is that transparent?

3 MS. JOHNSTON: Object to the  
 4 form.

5 THE WITNESS: Well, it shows  
 6 you -- it gives the reader a view into  
 7 the process of how conflicts are  
 8 either disclosed or resolved by the  
 9 publications committee of the Society  
 10 for Maternal-Fetal Medicine.

11 QUESTIONS BY MR. TRACEY:  
 12 Q. What was the process that was  
 13 used?

14 MS. JOHNSTON: Object to the  
 15 form. Asked and answered.

16 THE WITNESS: You know, I've  
 17 said, I think now this is my third  
 18 time saying it, I'm not familiar with  
 19 the exact process at the -- of the  
 20 publications committee for the Society  
 21 for Maternal-Fetal Medicine, but there  
 22 certainly is enough here to tell me  
 23 that this is -- this is considered  
 24 very carefully by the members of the  
 25 publication committee and the authors

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1 of this document.

2 QUESTIONS BY MR. TRACEY:  
 3 Q. Whoever they are?

4 MS. JOHNSTON: Object to the  
 5 form.

6 THE WITNESS: Yes.

7 QUESTIONS BY MR. TRACEY:  
 8 Q. And we don't know who the  
 9 authors are, we don't know who the committee  
 10 members are, we don't know who the executive  
 11 board is that resolved these conflicts or  
 12 what the process was, do we, ma'am?

13 MS. JOHNSTON: Objection.  
 14 Compound.

15 THE WITNESS: Well, we  
 16 certainly could look up who was on the  
 17 executive board in 2017. That  
 18 information is public.

19 And I know that the committee  
 20 members of the -- of the Society for  
 21 their publications committee, that  
 22 could be found out at this point.

23 And also, I assume that --

24 QUESTIONS BY MR. TRACEY:  
 25 Q. By who --

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1 A. -- the authors could be --  
 2 could be identified as well.

3 Q. How would you do that? I want  
 4 to do that, Dr. D'Alton.

5 How would I identify who the  
 6 authors and committee members were that  
 7 authored this paper?

8 MS. JOHNSTON: Object to the  
 9 form.

10 THE WITNESS: I would refer you  
 11 to the last sentence on this page  
 12 which is, "All questions, comments  
 13 regarding the document should be  
 14 referred to the SMFM publications  
 15 committee."

16 QUESTIONS BY MR. TRACEY:  
 17 Q. And you think if I write them,  
 18 they'll tell me that?

19 A. I can't speak for them,  
 20 Mr. Tracey, but I can only share with you  
 21 what's on this document; that if you have  
 22 questions or comments that you should be able  
 23 to contact them.

24 Q. Why all the secrecy, ma'am?  
 25 Why not put the names on the paper with the

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1 conflicts disclosed like every other journal  
2 does?

3 MS. JOHNSTON: Object to the  
4 form. This is well outside the scope  
5 of Dr. D'Alton's report and testimony.

6 THE WITNESS: I can't comment  
7 on what every other journal does with  
8 their statements.

9 I can just share what they've  
10 said about their own process at SMFM.

11 QUESTIONS BY MR. TRACEY:  
12 Q. Are you on any other journals  
13 that failed to disclose the authors of  
14 papers?

15 MS. JOHNSTON: Object to the  
16 form.

17 THE WITNESS: Well, this is a  
18 statement on behalf of the Society, so  
19 certainly there are publications that  
20 publish the recommendations of the  
21 Society but don't disclose the  
22 individual authors but describe their  
23 policy.

24 QUESTIONS BY MR. TRACEY:  
25 Q. And as we sit here right now,

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1 nobody reading this has any idea whether the  
2 authors that are committee members,  
3 historically or at the time or after this,  
4 were taking money from industry?

5 MS. JOHNSTON: Objection.

6 QUESTIONS BY MR. TRACEY:  
7 Q. We have no way of knowing that?

8 MS. JOHNSTON: Object to the  
9 form.

10 THE WITNESS: That is not  
11 disclosed here, except their  
12 publications process, and that  
13 questions could be referred to the  
14 publications committee if there was  
15 concerns or questions.

16 QUESTIONS BY MR. TRACEY:  
17 Q. That feels like a Soviet Bloc  
18 bureaucrat -- bureaucracy, doesn't it?

19 MS. JOHNSTON: Object to the  
20 form.

21 THE WITNESS: I would not liken  
22 the Society statement to the Soviet  
23 Union, a Soviet Bloc.

24 QUESTIONS BY MR. TRACEY:  
25 Q. Well, I meant trying to get at

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1 the information. Do we have to -- do we have  
2 to request something? We have to request the  
3 identity? We have to request whether they've  
4 been paid by industry?

5 MS. JOHNSTON: You can wait for  
6 him to ask you a question and a single  
7 one.

8 QUESTIONS BY MR. TRACEY:  
9 Q. Have you ever seen that before,  
10 ma'am, where a journal refused to disclose  
11 the financial conflict of interest and the  
12 authors of a paper?

13 MS. JOHNSTON: Object to the  
14 form. Asked and answered.

15 QUESTIONS BY MR. TRACEY:  
16 Q. In --  
17 A. I don't see any evidence of a  
18 refusal here to declare their conflict of  
19 interest. They state very clearly if you  
20 have questions about this document, they  
21 should -- or comments, they should be  
22 referred to the SMFM publications committee.

23 Q. Okay. Fair enough. I think  
24 I'll do that.

25 (D'Alton Exhibit 937 marked for

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1 identification.)

2 QUESTIONS BY MR. TRACEY:  
3 Q. Let's turn to the response  
4 from -- this is Exhibit 937.

5 This is the response from  
6 Drs. Olsen and Liew to the Society's  
7 publication.

8 MS. JOHNSTON: We're just  
9 getting a copy, Sean.

10 THE WITNESS: Sorry, we're just  
11 getting a copy.

12 QUESTIONS BY MR. TRACEY:  
13 Q. Yeah, I'm going to ask you some  
14 questions that you don't need the paper for,  
15 for a second, while he's doing that.

16 Did you cite the response in  
17 your report?

18 MS. JOHNSTON: And, Doctor,  
19 you've got a copy of your report, if  
20 you need to take a look.

21 THE WITNESS: I don't believe  
22 that I did cite this.

23 QUESTIONS BY MR. TRACEY:  
24 Q. Why not?

25 MS. JOHNSTON: Object to the

<p style="text-align: right;">Page 246</p> <p>1 form.</p> <p>2 THE WITNESS: I don't really</p> <p>3 recall why I didn't. I would have to</p> <p>4 read this. I don't recall the details</p> <p>5 of this -- of this response.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Have you ever seen it before</p> <p>8 today?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: Quite honestly, I</p> <p>12 can't tell you whether I have or</p> <p>13 not -- or not have seen it before</p> <p>14 today. I can't recall it at this</p> <p>15 moment at all.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. Well, let's look at it, then,</p> <p>18 together. It's called -- this is published</p> <p>19 in Expert Opinion on Drug Safety. The name</p> <p>20 of it is, "Fetal programming of mental health</p> <p>21 by acetaminophen? Response to the SMFM</p> <p>22 statement: Prenatal acetaminophen use and</p> <p>23 ADHD."</p> <p>24 And the authors are Drs. Olsen</p> <p>25 and Liew, correct?</p>	<p style="text-align: right;">Page 248</p> <p>1 What I said was you recognized</p> <p>2 these as being two researchers who have</p> <p>3 designed studies looking at the precise issue</p> <p>4 that you and I have been talking about all</p> <p>5 day?</p> <p>6 MS. JOHNSTON: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: We certainly have</p> <p>9 talked about a number of issues all</p> <p>10 day, but this is one of them, yes.</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Okay. These are scientists</p> <p>13 that have done the work and designed the</p> <p>14 studies to look at whether or not</p> <p>15 acetaminophen is associated with or causes</p> <p>16 ADHD or ASD, right?</p> <p>17 MS. JOHNSTON: Object to the</p> <p>18 form. Asked and answered.</p> <p>19 THE WITNESS: They are</p> <p>20 epidemiologists. They're not</p> <p>21 clinicians, and they have done</p> <p>22 research that they have published on</p> <p>23 the association between acetaminophen</p> <p>24 and ADHD and ASD.</p> <p>25</p>
<p style="text-align: right;">Page 247</p> <p>1 A. Yes.</p> <p>2 Q. Now, you recognize them as</p> <p>3 being the authors -- or being researchers who</p> <p>4 actually did design and study whether or not</p> <p>5 acetaminophen causes ADHD or autism.</p> <p>6 MS. JOHNSTON: Object to the --</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. Right?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: Well, I don't</p> <p>12 believe they designed the Danish</p> <p>13 cohort. They used the Danish cohort</p> <p>14 to design their study, but they didn't</p> <p>15 design the Danish cohort as I reviewed</p> <p>16 their publications.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. Yeah, I didn't say they</p> <p>19 designed the cohort. I said they designed</p> <p>20 their study.</p> <p>21 A. Okay. Then I --</p> <p>22 Q. The design.</p> <p>23 A. Then I mis -- I'm sorry, I</p> <p>24 misheard you.</p> <p>25 Q. Yeah.</p>	<p style="text-align: right;">Page 249</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. When you said they're not</p> <p>3 clinicians, are you trying to diminish their</p> <p>4 credentials?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: Absolutely no way</p> <p>8 am I trying to diminish their</p> <p>9 credentials.</p> <p>10 But what I would say to you is</p> <p>11 that -- and to them, if I ever had the</p> <p>12 opportunity to speak with them -- that</p> <p>13 the clinical impact and the clinical</p> <p>14 voice is very important in considering</p> <p>15 maternal use of acetaminophen in</p> <p>16 pregnancy because obstetrician,</p> <p>17 gynecologists and health care</p> <p>18 professionals who care for pregnant</p> <p>19 patients are the ones who are speaking</p> <p>20 to patients about the use of this --</p> <p>21 of this medication in pregnancy for</p> <p>22 pain and for fever.</p> <p>23 QUESTIONS BY MR. TRACEY:</p> <p>24 Q. What about the mother's voice?</p> <p>25 Should the mother's voice be heard?</p>

<p style="text-align: right;">Page 250</p> <p>1 MS. JOHNSTON: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: The obstetrician,</p> <p>4 gynecologists don't do anything</p> <p>5 without the mother's voice. The</p> <p>6 mother's voice is so important in</p> <p>7 the -- in the role of an obstetrician,</p> <p>8 gynecologist. And part of their daily</p> <p>9 work is being an advocate for the</p> <p>10 mothers that they take care of and</p> <p>11 doing a risk/benefit analysis when</p> <p>12 they are faced with whether to use or</p> <p>13 recommend a drug during pregnancy.</p> <p>14 So they are very much involved</p> <p>15 and in tune on a daily basis with the</p> <p>16 mother's voice.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. And in order for the mother's</p> <p>19 voice to be heard, the mother has to know</p> <p>20 what the risks and the benefits are, right?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: Well, first of</p> <p>24 all, they have to know if the -- if</p> <p>25 there's a need for the -- need for a</p>	<p style="text-align: right;">Page 252</p> <p>1 Q. Because in the end,</p> <p>2 Dr. D'Alton, it's not your decision to make;</p> <p>3 it's the mother's, isn't it?</p> <p>4 A. Well, it's a shared decision,</p> <p>5 usually, between the physician or health care</p> <p>6 professional and the patient. Clearly the</p> <p>7 end result of that is whether a patient would</p> <p>8 take the medicine based on my recommendation</p> <p>9 after a full risk assessment was done, based</p> <p>10 on what the indications were, understanding</p> <p>11 her personal, her medical history, the risk</p> <p>12 of the particular symptomatology of fever and</p> <p>13 sign -- symptom of pain and then sign of</p> <p>14 fever must be taken into account.</p> <p>15 Q. But in the end, it's her</p> <p>16 decision; not yours?</p> <p>17 MS. JOHNSTON: Object to the</p> <p>18 form. Asked and answered.</p> <p>19 THE WITNESS: In the end -- we</p> <p>20 always talk about shared decision</p> <p>21 in obstetrics and gynecology, and the</p> <p>22 process for decision is generally</p> <p>23 arrived to together by the health care</p> <p>24 professional and the patient.</p> <p>25 You're right, sometimes --</p>
<p style="text-align: right;">Page 251</p> <p>1 medication. And certainly it's</p> <p>2 recommended by all that medication</p> <p>3 should not be used routinely in</p> <p>4 pregnancy, that it should be used</p> <p>5 after a risk/benefit analysis is done</p> <p>6 and -- with the patient and physician,</p> <p>7 and that the lowest dose of a</p> <p>8 medication for the shortest period of</p> <p>9 time should be used if there is an</p> <p>10 indication for that medicine.</p> <p>11 So this is daily practice for</p> <p>12 obstetrician, gynecologists, and is</p> <p>13 not daily practice for</p> <p>14 epidemiologists. And that's why it's</p> <p>15 so important that there is a clinical</p> <p>16 voice.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. Well --</p> <p>19 A. And a mother's voice. And a</p> <p>20 mother's voice. You asked me about mother's</p> <p>21 voice, which is very much --</p> <p>22 Q. I did.</p> <p>23 A. -- fore -- which is very much</p> <p>24 forefront by health care professionals who</p> <p>25 are -- who are managing pregnancy.</p>	<p style="text-align: right;">Page 253</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Doctor --</p> <p>3 A. -- sometimes patients will</p> <p>4 decide not to -- not to take the</p> <p>5 recommendation of a physician, a health care</p> <p>6 professional, but in my view with use of</p> <p>7 Tylenol for many decades, that is</p> <p>8 extraordinarily rare. I don't even remember</p> <p>9 a case where that has happened to me in my</p> <p>10 clinical practice.</p> <p>11 MR. TRACEY: Objection.</p> <p>12 Nonresponsive.</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. Dr. D'Alton, you can't</p> <p>15 force-feed a woman Tylenol, can you?</p> <p>16 MS. JOHNSTON: Object to the</p> <p>17 form.</p> <p>18 THE WITNESS: Well, I mean,</p> <p>19 to ask me that I would even consider</p> <p>20 force-feeding a woman Tylenol is just</p> <p>21 not what I do.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. No, it's a --</p> <p>24 A. I don't force-feed anyone</p> <p>25 anything.</p>

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1 Q. Yes. It's a ridiculous  
2 question to try to make my point, which you  
3 seem to be antagonistic towards.  
4 And it's this, it is the  
5 mother's decision, not yours, whether or not  
6 after a complete risk/benefit analysis she is  
7 going to take Tylenol or not, right?  
8 MS. JOHNSTON: Object to the  
9 form. Asked and answered.  
10 THE WITNESS: Ultimately it is  
11 her decision, and I would say I'm not  
12 being antagonistic towards this. I'm  
13 very familiar with the shared  
14 decision-making between a health care  
15 professional and the patient, but  
16 ultimately the decision about whether  
17 to take the recommendations  
18 following a -- following a detailed  
19 risk/benefit analysis is the patient.  
20 QUESTIONS BY MR. TRACEY:  
21 Q. Well, the patient might not  
22 agree with your assessment, and they might  
23 get a second opinion from another  
24 maternal-fetal expert, true?  
25 MS. JOHNSTON: Object to the

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1 form.  
2 THE WITNESS: I think that  
3 could be true in certain instances  
4 where there's a rare situation. I  
5 have never seen that encountered or  
6 heard about it with respect to  
7 prenatal Ty -- Tylenol.  
8 QUESTIONS BY MR. TRACEY:  
9 Q. Do you think it's inconceivable  
10 that another obstetrician might have a  
11 opinion that's different than yours?  
12 MS. JOHNSTON: Object to the  
13 form.  
14 THE WITNESS: Nothing is  
15 inconceivable, but I have not heard of  
16 anybody who's practicing obstetrics  
17 and gynecology who's an obstetrician  
18 who deals with pregnant patients to  
19 have an opposing view.  
20 QUESTIONS BY MR. TRACEY:  
21 Q. You're not aware of any  
22 practicing obstetrician, gynecologist that  
23 thinks differently about Tylenol than you?  
24 MS. JOHNSTON: Object to the  
25 form.

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1 THE WITNESS: Well, I would say  
2 that Dr. Hugh Taylor is on the  
3 document as an author with -- in the  
4 Bauer 2021 statement. Dr. Taylor is a  
5 counterpart of mine. He's a chair of  
6 obstetrics and gynecology at Yale  
7 University, but he does reproductive  
8 endocrinologist -- endocrinology and  
9 to my knowledge does not practice  
10 obstetrics and does not treat pregnant  
11 patients.  
12 So there certainly is an  
13 OB/GYN -- one OB/GYN that I saw on  
14 the -- on the documents that's by  
15 Bauer, and in the signatories of the  
16 document by Bauer, there's two that I  
17 could find clinical people from, I  
18 believe, it's Copenhagen that signed  
19 on to this document.  
20 I did not see any evidence of  
21 any other practicing obstetrician,  
22 gynecologist who sees patients in  
23 pregnancy sign this document.  
24 QUESTIONS BY MR. TRACEY:  
25 Q. All right. So you've come up

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1 with three.  
2 A. Well, they signed the document,  
3 and I assume that they agree with it. I  
4 don't know the process for signing and the  
5 process for being an author on that document.  
6 Q. Okay. If a practicing  
7 obstetrician, gynecologist shared an opinion  
8 with a patient that they believed there was a  
9 real, legitimate risk of a neurodevelopmental  
10 delay occurring with exposure to Tylenol, do  
11 you think that would be malpractice?  
12 MS. JOHNSTON: Object to the  
13 form and hypothetical.  
14 THE WITNESS: I'm not sure I  
15 would say it's malpractice. What I  
16 would say it's giving misinformation  
17 to patients, as I'm aware of it.  
18 Malpractice is the practice of  
19 medicine, as I did -- did they  
20 actually tell a patient not to take  
21 Tylenol when there was an indication  
22 for the use of Tylenol because of  
23 neurodevelopmental issues, which can  
24 be very broad.  
25 And I'm not aware of other --

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1 what neurodevelopmental issues you're  
2 talking about. I assume it's ASD and  
3 ADHD, but I can't be certain based on  
4 your question.  
5 QUESTIONS BY MR. TRACEY:  
6 Q. Okay. Let's look at what  
7 the -- Dr. Olsen and Liew had to say in  
8 response to the Society for Maternal-Fetal  
9 Medicine, and we'll just start with the  
10 introduction.  
11 It says -- they say,  
12 "Acetaminophen, or paracetamol, is used by  
13 many who often consider the drug to be safe  
14 when taken" --  
15 A. I'm sorry, where are we? I  
16 don't -- sorry. I don't know where you are  
17 here. Okay. Just give me a moment to follow  
18 along with you.  
19 Q. Are you ready?  
20 MS. JOHNSTON: And you can take  
21 your time, Doctor.  
22 THE WITNESS: I'm ready to  
23 follow this part. As I shared with  
24 you, I don't remember this document,  
25 and I can't recall if I considered it

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1 in this -- in my review.  
2 QUESTIONS BY MR. TRACEY:  
3 Q. Understood. We're going to do  
4 it together.  
5 A. Thank you.  
6 Q. They say, "Acetaminophen, or  
7 paracetamol, is used by many who often  
8 consider the drug to be safe when taken in  
9 recommended doses, even for pregnant women.  
10 These drugs do not affect birth weight or  
11 cause congenital malformations, but several  
12 recent studies show a link between prenatal  
13 intake of acetaminophen and behavioral/  
14 functional defects in the exposed offspring  
15 later.  
16 "Should we be concerned about  
17 that? The Society for Maternal-Fetal  
18 Medicine committee thinks not, or at least  
19 suggests that these findings should have no  
20 regulatory consequences at present. We  
21 disagree."  
22 Did you follow along with that?  
23 A. I did.  
24 Q. They go on to say that, "The  
25 existing evidence is based on observational

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1 data from several cohorts and different  
2 analytical options have been used. These  
3 research findings have increased the  
4 probability that the association is causal,  
5 and it is too simple and not justified to  
6 explain away the possibility of causality by  
7 mentioning confounding, especially  
8 confounding by indication. It has to be  
9 supported by stronger evidence, not just  
10 opinions."  
11 Did you follow along with that?  
12 A. Yes.  
13 Q. Do you remember what your own  
14 paper said about the weakness of opinion  
15 evidence?  
16 MS. JOHNSTON: Object to the  
17 form.  
18 THE WITNESS: Yes, I remember  
19 what it says. I'll have to look at  
20 my report to -- because I believe I  
21 was quoting a -- another article in  
22 that, where observational trials are  
23 usually very weak in assigning  
24 causation in other drug --  
25

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1 QUESTIONS BY MR. TRACEY:  
2 Q. Ma'am, I think you're --  
3 A. -- in pregnancy.  
4 Q. I think you're confused  
5 about --  
6 A. Okay.  
7 Q. -- the paper I'm talking about.  
8 A. Okay.  
9 Q. I'm talking about your own  
10 paper, your own study that you did on ACOG  
11 bulletins and the strength of the evidence  
12 that supports them.  
13 Do you remember that paper?  
14 The first author was Jason Wright.  
15 A. Yes. I didn't know that's what  
16 you were talking about, so let me pull that  
17 out.  
18 Q. Sorry.  
19 A. Okay. It's no problem at all.  
20 Let me pull it out.  
21 Q. There's no need to pull it  
22 out --  
23 MS. JOHNSTON: If you need to  
24 look at the document, you certainly  
25 can.

<p style="text-align: right;">Page 262</p> <p>1 THE WITNESS: That's not Micah</p> <p>2 Wright. That's not Wright.</p> <p>3 It was talking about documents</p> <p>4 produced by ACOG. I don't remember it</p> <p>5 was talking about observational</p> <p>6 trials.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. It was talking about ACOG</p> <p>9 practice bull -- bulletins and the level of</p> <p>10 evidence to support them and the fact that</p> <p>11 over 30 percent of the ACOG practice</p> <p>12 bulletins were opinion evidence, which is the</p> <p>13 weakest form of evidence.</p> <p>14 Do you recall that now?</p> <p>15 A. I do.</p> <p>16 MS. JOHNSTON: Object to the</p> <p>17 form.</p> <p>18 THE WITNESS: I'm sorry, I do.</p> <p>19 But I got confused because you said I</p> <p>20 made a statement about observational</p> <p>21 trials.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. Okay.</p> <p>24 A. I -- it was not a statement</p> <p>25 about observational trials. It was an</p>	<p style="text-align: right;">Page 264</p> <p>1 at that document, do you agree with</p> <p>2 this, do you agree with that.</p> <p>3 What are you actually asking</p> <p>4 Dr. D'Alton to do right now? And</p> <p>5 which document should she be looking</p> <p>6 at?</p> <p>7 MR. TRACEY: I don't know</p> <p>8 how to say -- I don't know how to say</p> <p>9 it any more clearly.</p> <p>10 MS. JOHNSTON: I mean, all</p> <p>11 right. But --</p> <p>12 MR. TRACEY: The Society --</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. Dr. D'Alton, are you following</p> <p>15 me?</p> <p>16 A. I believe that I am. I believe</p> <p>17 that you're asking me to look at the Society</p> <p>18 document.</p> <p>19 Q. Yes. And I want you to see if</p> <p>20 the Society did what Drs. Olsen and Liew said</p> <p>21 they must do.</p> <p>22 MS. JOHNSTON: Object to the</p> <p>23 form.</p> <p>24 THE WITNESS: Well, I think</p> <p>25 there's much evidence of that</p>
<p style="text-align: right;">Page 263</p> <p>1 article that I was a coauthor on about the</p> <p>2 evidence underlying the ACOG publication</p> <p>3 documents, not the -- my comments on</p> <p>4 observational trials.</p> <p>5 Q. Okay. Doctor, I'm confused. I</p> <p>6 think I'll move on.</p> <p>7 A. Okay.</p> <p>8 Q. What I do want you to find for</p> <p>9 me, though, in the Society statement is where</p> <p>10 their evidence is of confounding that the</p> <p>11 study authors are asking for.</p> <p>12 Do you see where Olsen and Liew</p> <p>13 say, "It is too simple and not justified to</p> <p>14 explain away the possibility of causality by</p> <p>15 mentioning confounding, especially</p> <p>16 confounding by indication. It has to be</p> <p>17 supported by stronger evidence, not just</p> <p>18 opinions"?</p> <p>19 What I would like you to do is</p> <p>20 pull out the Society's statement and show us</p> <p>21 where their evidence is.</p> <p>22 MS. JOHNSTON: And, Sean, I'm</p> <p>23 just going to object and ask you to</p> <p>24 ask a question. I'm following along,</p> <p>25 and I see, look at this document, look</p>	<p style="text-align: right;">Page 265</p> <p>1 throughout this -- or in the -- in</p> <p>2 that -- in that paragraph on the</p> <p>3 second page of the SMFM document.</p> <p>4 They said, "Potential</p> <p>5 confounders," and they listed them,</p> <p>6 "recall bias, interview bias and</p> <p>7 failure to adjust for multiple</p> <p>8 testing."</p> <p>9 They also said later that</p> <p>10 the -- earlier that the diagnosis of</p> <p>11 these illnesses, especially ADHD,</p> <p>12 continues to evolve and the --</p> <p>13 especially ADHD.</p> <p>14 And furthermore, because of the</p> <p>15 cause or causes of AD -- because of</p> <p>16 the cause or causes of ADHD are</p> <p>17 unknown, there's potential -- other</p> <p>18 potential and postnatal confounders</p> <p>19 such as environmental exposures and</p> <p>20 genetic predisposition that these</p> <p>21 retrospective analysis are unable to</p> <p>22 measure.</p> <p>23 So I think not only did they</p> <p>24 talk about confounders, they talked</p> <p>25 about the issue with accurate</p>

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1 diagnosis of the condition. That is  
 2 an issue in some of the articles that  
 3 have been published. It's based on  
 4 screening studies, not based on  
 5 diagnosis. They do address that.  
 6 Secondly, there's inadequate  
 7 information about dosage, and they  
 8 talk about assigning dosage based on  
 9 recall bias and interview bias is  
 10 not -- is not appropriate, is a  
 11 weakness in studies, and especially  
 12 genetic confounders.  
 13 I mean, what we do know about  
 14 ASD and ADHD is that the predominant  
 15 cause of ASD and ADHD is genetic and  
 16 not to control for genetic confounders  
 17 that is not present in any of the  
 18 studies related to ASD is not  
 19 appropriate.  
 20 QUESTIONS BY MR. TRACEY:  
 21 Q. Are you done?  
 22 A. I can go on, if you like.  
 23 Q. Let me ask you this. You said  
 24 a lot. I have some questions about what you  
 25 said.

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1 Do you think that the mere  
 2 utterance of the term "confounding" is some  
 3 sort of magic wand that makes an effect in a  
 4 study go away?  
 5 MS. JOHNSTON: Object to the  
 6 form.  
 7 THE WITNESS: Of course not,  
 8 but I was answering a different  
 9 question what the Society said about  
 10 this earlier when I went on about  
 11 that.  
 12 QUESTIONS BY MR. TRACEY:  
 13 Q. Yes, ma'am.  
 14 It is not some magical wand  
 15 when you simply enter -- utter the  
 16 incantation "confounding," that is not a  
 17 scientific tool that erases a positive  
 18 finding, is it?  
 19 MS. JOHNSTON: Object to the  
 20 form. Asked and answered.  
 21 THE WITNESS: Well, I think  
 22 it -- it does, especially -- it may  
 23 erase the finding and especially with  
 24 relation -- with respect to genetic  
 25 confounding because certainly we know

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1 that -- as I've stated, the  
 2 predominant cause of ASD and ADHD is  
 3 genetic.  
 4 PRAC, which is the European  
 5 pharmacologic --  
 6 QUESTIONS BY MR. TRACEY:  
 7 Q. Can you stay with my question?  
 8 MS. JOHNSTON: Wait, no.  
 9 THE WITNESS: Well, I'm trying  
 10 to answer your question.  
 11 MS. JOHNSTON: And, yeah. And,  
 12 Dr. D'Alton, you can finish your  
 13 answer.  
 14 QUESTIONS BY MR. TRACEY:  
 15 Q. What are you answering?  
 16 A. I'm answering about  
 17 confoundings and genetic confounders, which  
 18 is so important in my opinion in the --  
 19 especially genetic confounders in determining  
 20 whether a prenatal exposure is associated  
 21 with ASD or ADHD because it is the  
 22 predominant cause.  
 23 Q. Okay. But I need to take this  
 24 methodically in bite sizes, Dr. D'Alton.  
 25 How much of the confounding,

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1 according to the maternal -- the Society for  
 2 Maternal-Fetal Medicine was attributed to  
 3 misclassification?  
 4 MS. JOHNSTON: Object to the  
 5 form.  
 6 THE WITNESS: I mean, they  
 7 don't detail that with each one of  
 8 those. They just address their  
 9 general concern about the totality of  
 10 the publications that were present  
 11 in -- prior to this publication in  
 12 2017.  
 13 QUESTIONS BY MR. TRACEY:  
 14 Q. How much of the effect is  
 15 explained away by other forms of confounding  
 16 that you mentioned? What does the Society  
 17 say? Give me numbers.  
 18 MS. JOHNSTON: Object to the  
 19 form.  
 20 THE WITNESS: Well, I can't  
 21 give you numbers because the Society  
 22 doesn't publish numbers. So for me to  
 23 make up numbers and be speculative  
 24 about this would not be appropriate,  
 25 Mr. Tracey.

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1 QUESTIONS BY MR. TRACEY:

2 Q. No, ma'am, it would not be. It

3 would be speculation for anybody to claim

4 that the confounders that the Society has

5 identified had any impact on the findings

6 because there's no evidence of that, is

7 there?

8 MS. JOHNSTON: Object to the

9 form.

10 THE WITNESS: I disagree with

11 you, Mr. Tracey. There is strong

12 evidence for -- not at this point, but

13 in -- later on that -- and certainly

14 was at this point in 2017 by Ystrom,

15 which show that a negative control,

16 which is also a methodologic measure

17 of controlling for genetics, was where

18 paternal use of acetaminophen was

19 associated with ADHD.

20 And subsequent to that, there

21 was a Gustavson article --

22 QUESTIONS BY MR. TRACEY:

23 Q. Wait. Wait a second. Wait a

24 second. We got to stay with one subject at a

25 time, Doctor. I'm on --

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1 MS. JOHNSTON: Well, no, no,

2 no. No, no, no.

3 MR. TRACEY: I'm on --

4 MS. JOHNSTON: Sean, no.

5 You've done this all day long.

6 MR. TRACEY: I'm on the

7 Society --

8 MS. JOHNSTON: Sean, you've

9 done this all day long, and you've

10 specifically asked her to identify --

11 MR. TRACEY: I asked her what

12 was in the Society response.

13 MS. JOHNSTON: -- and she was

14 in the process of answering you, Sean.

15 MR. TRACEY: No. She was in

16 the process of adding stuff.

17 THE WITNESS: Well, Mr. Tracey,

18 I don't believe that I was. You asked

19 me what was the evidence for genetic

20 confounders.

21 QUESTIONS BY MR. TRACEY:

22 Q. Since then.

23 MS. JOHNSTON: We're not going

24 to do this.

25

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1 QUESTIONS BY MR. TRACEY:

2 Q. You said since then, Doctor.

3 MS. JOHNSTON: Sean, she's

4 going to finish her answer, and then

5 you can ask a different question, and

6 if you and I need to have a separate

7 discussion about this, we absolutely

8 can.

9 But you've called Dr. D'Alton

10 "ma'am" all day, and you've

11 consistently interrupted her, so I

12 would like you to please show the

13 witness some respect and allow her to

14 answer the questions you're asking.

15 MR. TRACEY: I would expect

16 Dr. D'Alton and you to respect the

17 system and not filibuster my

18 questions. That's what I would expect

19 out of you as an officer of the court.

20 MS. JOHNSTON: Dr. D'Alton, you

21 can finish your answer.

22 THE WITNESS: I've tried to

23 show you respect all day, Mr. Tracey,

24 and the fact that you don't believe I

25 have is troubling to me, and so I've

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1 done my best to answer the questions

2 that you have posed to me.

3 And the question I was

4 answering was about genetic

5 confounding. And you asked me not

6 about just this, but you asked me what

7 evidence is there that confounding

8 would change anything. So if I --

9 QUESTIONS BY MR. TRACEY:

10 Q. Yes.

11 A. -- misunderstood your question,

12 I apologize. But I was giving you my answer

13 with respect to how important, in my opinion,

14 genetic confounding is.

15 Q. But my question is very

16 specific, Doctor. I want to know how much of

17 the effect that we see in the studies is

18 mathematically attributed to the confounding

19 that you claim exists.

20 A. Well --

21 MS. JOHNSTON: Object to the

22 form.

23 THE WITNESS: In the studies,

24 there's no study that looks at genetic

25 confounding with respect to ASD.

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1 In -- with respect to ADHD, the  
 2 only one that used an appropriate  
 3 negative control was Ystrom, which  
 4 showed that paternal use of  
 5 acetaminophen was also a -- pre -- six  
 6 months prior to pregnancy was  
 7 associated and was exactly the same  
 8 risk as -- or higher than those with  
 9 maternal use of acetaminophen during  
 10 pregnancy.  
 11 And then those authors in the  
 12 MoBa cohort, from the Norwegian  
 13 cohort, went on in 2021 to further  
 14 evaluate in a better way genetic  
 15 confounding and showed that it  
 16 eliminated the risk of an association  
 17 of prenatal ingestion of maternal  
 18 acetaminophen and ADHD and ASD.  
 19 QUESTIONS BY MR. TRACEY:  
 20 Q. Are you finished?  
 21 A. I finished my answer so far on  
 22 genetic confounding, yes.  
 23 Q. You don't have any idea,  
 24 Doctor, of what percentage of the effect that  
 25 we see in the studies is attributable, if

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1 any, to the confounding you've identified, do  
 2 you?  
 3 MS. JOHNSTON: Object to the  
 4 form. Asked and answered.  
 5 THE WITNESS: Well, the problem  
 6 is that the majority of the studies  
 7 didn't adjust for genetic confounders,  
 8 and when they did, that --  
 9 QUESTIONS BY MR. TRACEY:  
 10 Q. Can you set genetics aside for  
 11 a second? I'll get to that.  
 12 MS. JOHNSTON: Dr. D'Alton --  
 13 QUESTIONS BY MR. TRACEY:  
 14 Q. But the other confounders.  
 15 MS. JOHNSTON: Dr. D'Alton.  
 16 Dr. D'Alton, please finish your  
 17 answer.  
 18 THE WITNESS: I mean,  
 19 Mr. Tracey, you got to consider  
 20 genetic confounders, which is one of  
 21 the confounders.  
 22 QUESTIONS BY MR. TRACEY:  
 23 Q. I agree.  
 24 A. Okay.  
 25 Q. I agree with you.

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1 A. So --  
 2 Q. But I'm trying to do this in a  
 3 methodical way.  
 4 MS. JOHNSTON: Okay. Well,  
 5 we're going to go back to the last  
 6 question, and Dr. D'Alton is going to  
 7 finish answering it, and then you can  
 8 ask another one.  
 9 Were you finished with your  
 10 answer, Dr. D'Alton?  
 11 THE WITNESS: I'm sorry, I  
 12 don't remember the question.  
 13 MS. JOHNSTON: I don't blame  
 14 you.  
 15 QUESTIONS BY MR. TRACEY:  
 16 Q. Dr. D'Alton, do you have any  
 17 evidence -- here is my question. Any  
 18 evidence for any of the confounding that you  
 19 claim exists as to what percentage of the  
 20 positive effect between acetaminophen and  
 21 ADHD and ASD is attributed to those  
 22 confounders?  
 23 MS. JOHNSTON: Object to the  
 24 form. Asked and partially answered.  
 25 THE WITNESS: Well, as I've

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1 said with confounding, it eliminated  
 2 the risk. So when the appropriate  
 3 adjustment was made for confounders,  
 4 it eliminated the risk.  
 5 QUESTIONS BY MR. TRACEY:  
 6 Q. Okay. You're talking about one  
 7 study now, Gustavson, right?  
 8 A. No, I'm talking about two  
 9 studies. I'm talking about the negative  
 10 control study that was done by Ystrom, and  
 11 I'm showing that a paternal -- maternal --  
 12 excuse me, paternal use of acetaminophen that  
 13 was taken six months prior to pregnancy had a  
 14 higher risk of ADHD than maternal use of  
 15 acetaminophen during pregnancy.  
 16 Q. What did the authors of Ystrom  
 17 attribute that to, ma'am?  
 18 A. They were very concerned about  
 19 this, which is in -- why they went on and did  
 20 even a better methodologic study with  
 21 Gustavson as the leader author in 20 -- I  
 22 can't remember. I think it was 2021 -- where  
 23 they addressed further genetic confounding.  
 24 And they had to consider  
 25 genetic confounding as the dominant cause

<p style="text-align: right;">Page 278</p> <p>1 of the reason why paternal use of 2 acetaminophen was more associated with ADHD 3 than maternal use of acetaminophen. 4 Q. Did you see what Dr. Baccarelli 5 had to say about that in his rebuttal report, 6 Doctor? 7 MS. JOHNSTON: Object to the 8 form. 9 And, Sean, I was trying to jump 10 in and just say, we've been going for 11 hour, five, so can we -- can we take a 12 break when you wrap this line up? 13 MR. TRACEY: Yeah. Yes. 14 QUESTIONS BY MR. TRACEY: 15 Q. Did you see what Dr. Baccarelli 16 said about the sib-pair studies in his 17 rebuttal? 18 MS. JOHNSTON: Object to -- 19 THE WITNESS: I can't remember 20 what he said about it offhand. I'd be 21 happy to look at it and see what he 22 said in his rebuttal. I've read it, 23 but I can't remember the specifics 24 that he had on that. 25</p>	<p style="text-align: right;">Page 280</p> <p>1 asking about the confidence intervals. 2 There's -- this is not an opinion question. 3 Do you recall what the 4 confidence intervals in the Gustavson paper 5 in the sib-pair cohort were? 6 MS. JOHNSTON: Object to the 7 form. 8 THE WITNESS: I would have to 9 look it up. I can't recall that at 10 this moment. 11 QUESTIONS BY MR. TRACEY: 12 Q. Well, you said you thought they 13 were statistically significant. 14 Remember that a minute ago? 15 A. As far as I remember, they 16 eliminated the risk, but I'd have to look 17 back to confirm that. 18 Q. And my question is, if you're 19 wrong, if they were not statistically 20 significant, would that change your opinion? 21 MS. JOHNSTON: Object to the 22 form. 23 THE WITNESS: No, it would not 24 change my opinion because the issue of 25 genetic confounding has not been</p>
<p style="text-align: right;">Page 279</p> <p>1 QUESTIONS BY MR. TRACEY: 2 Q. Do you remember whether the -- 3 whether the confidence intervals in the 4 sib-pair study crossed 1? 5 MS. JOHNSTON: Object to the 6 form. 7 THE WITNESS: I believe that it 8 was statistically significant. I'd 9 have to look back at it. 10 QUESTIONS BY MR. TRACEY: 11 Q. If it was not statistically 12 significant, what would that mean to you? 13 MS. JOHNSTON: Object to the 14 form, and I'm not following whether 15 we're talking about Dr. Baccarelli's 16 report. Maybe that's me. 17 If Dr. D'Alton knows where you 18 are, that's fine, but... 19 THE WITNESS: I am -- I 20 can't -- I can't remember what he said 21 about that, to be honest, Mr. Tracey -- 22 QUESTIONS BY MR. TRACEY: 23 Q. No -- 24 A. -- at this point. 25 Q. -- no. I'm asking -- I'm</p>	<p style="text-align: right;">Page 281</p> <p>1 studied enough in ASD and ADHD, and it 2 needs to be addressed substantially in 3 all studies related to A -- ADHD and 4 ASD because it is the dominant cause 5 of -- of ASD and ADHD. 6 QUESTIONS BY MR. TRACEY: 7 Q. I see. Let's finish up with 8 Liew and Olsen's response. 9 You mentioned negative control 10 studies. Let's see what the actual 11 researchers of those studies had to say. 12 They say, "Several analytical methods that 13 aim to minimize confounding bias have been 14 utilized in these studies, and findings from 15 a propensity score matched method, 16 sibling-controlled analysis, and negative 17 control comparison have all given consistent 18 results, providing additional evidence 19 against confounding as the primary reason to 20 explain away the possible fetal programming 21 of acetaminophen on brain function in 22 childhood." 23 Now, you are seeing this for 24 the first time today? 25 MS. JOHNSTON: Object to the</p>

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1 form.

2 THE WITNESS: As I shared with

3 you, I can't remember seeing this

4 before.

5 Have I seen it before? I may

6 have, but I can't recall it at this

7 point.

8 So let me just look at the

9 articles.

10 QUESTIONS BY MR. TRACEY:

11 Q. Do you know where Dr. Liew

12 works?

13 MS. JOHNSTON: And, Mary --

14 Dr. D'Alton, take your time. We'll

15 wait for you and ask a question again.

16 THE WITNESS: I've looked at

17 this, yes.

18 QUESTIONS BY MR. TRACEY:

19 Q. And this is the first time

20 you've seen it?

21 MS. JOHNSTON: Object to the

22 form. Asked and answered.

23 THE WITNESS: Mr. Tracey, I've

24 said it a number of times. I don't

25 know if it's the first time. I can't

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1 recall having seen it before. Whether

2 I have or not, I just don't know.

3 I can't answer that for you

4 right now.

5 QUESTIONS BY MR. TRACEY:

6 Q. So let me ask you this. How

7 did you -- what was your search strategy for

8 identifying relevant literature that you

9 gathered to write your report?

10 MS. JOHNSTON: Just really

11 quickly. Dr. D'Alton, you're going to

12 answer this because this is a pending

13 question.

14 But, Sean, it's my

15 understanding that you wanted to wrap

16 up on Liew and Olsen and then I asked

17 for a break six minutes ago.

18 MR. TRACEY: Yeah. You -- I'll

19 tell you what, I'll withdraw that

20 question.

21 MS. JOHNSTON: That's fine.

22 MR. TRACEY: Let's take the

23 break, and then we'll come back.

24 MS. JOHNSTON: Sounds good.

25 Thank you.

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1 THE WITNESS: Thank you.

2 VIDEOGRAPHER: The time right

3 now is 2:47 p.m. We are off the

4 record.

5 (Off the record at 2:47 p.m.)

6 VIDEOGRAPHER: The time right

7 now is 3:04 p.m. We are back on the

8 record.

9 MR. TRACEY: Ray, can you put

10 the Liew, Olsen reply back up? I

11 think it was Exhibit 937.

12 QUESTIONS BY MR. TRACEY:

13 Q. Dr. D'Alton, on the -- under

14 Section 4, there is -- it's -- next page,

15 yeah. There you go.

16 Well, keep going.

17 Yeah, there you go. Stop right

18 there.

19 Expert opinion to act or not to

20 act.

21 Do you see that, ma'am?

22 A. Yes.

23 Q. I want to see what they have to

24 say about this, expert opinion to act and not

25 to act.

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1 They say, "Whether actions are

2 recommended or not also depend upon the

3 consequences of doing something versus doing

4 nothing. In many situations, the

5 precautionary principle should be used and

6 the unborn child should benefit from the

7 doubt."

8 Do you agree with that?

9 MS. JOHNSTON: Object to the

10 form.

11 THE WITNESS: I think it

12 depends on how big the doubt is; and

13 in this case, I don't agree with that.

14 QUESTIONS BY MR. TRACEY:

15 Q. All right. They go on to say,

16 "Acetaminophen is often purchased over the

17 counter and used for minor symptoms or

18 discomfort where the treatment has no strong

19 indication and carries little risk for the

20 pregnant women."

21 Do you agree with that?

22 MS. JOHNSTON: Object to the

23 form.

24 THE WITNESS: No. In general,

25 I don't agree with that. I'm not

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1 aware of what data they're using to  
2 say symptoms are minor or the mother  
3 has discomfort, and there is no strong  
4 indication.  
5 As I've indicated to you  
6 multiple times today, medications  
7 should not be used without indication,  
8 without discussing it with a physician  
9 or a health care professional, and  
10 should be used for -- in the lowest  
11 dose and for the lowest -- and for the  
12 shortest amount of time.  
13 QUESTIONS BY MR. TRACEY:  
14 Q. But, Dr. D'Alton, do you know  
15 what the indications for acetaminophen are  
16 that are on the label?  
17 MS. JOHNSTON: Object to the  
18 form.  
19 THE WITNESS: I'll have to pull  
20 out the label to look at them, but  
21 there's a number of indications  
22 related mainly to pain and fever.  
23 QUESTIONS BY MR. TRACEY:  
24 Q. Okay. And do you recall the  
25 words "minor aches and pains" on the label?

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1 MS. JOHNSTON: Object to the  
2 form.  
3 THE WITNESS: At this point I  
4 don't remember that. I remember more  
5 about what it says about pregnancy.  
6 QUESTIONS BY MR. TRACEY:  
7 Q. Okay. What it says about  
8 pregnancy is nothing, right?  
9 A. Well, it does say --  
10 MS. JOHNSTON: Object to the  
11 form.  
12 THE WITNESS: Sorry.  
13 As I recall what it says about  
14 pregnancy is contact your doctor or  
15 health care professional prior to use.  
16 QUESTIONS BY MR. TRACEY:  
17 Q. And that's true of every single  
18 over-the-counter product in America because  
19 that's the law, right?  
20 MS. JOHNSTON: Object to the  
21 form.  
22 THE WITNESS: I honestly  
23 haven't looked at every single product  
24 in America. So I'm not a labeling  
25 expert or familiar with the laws.

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1 QUESTIONS BY MR. TRACEY:  
2 Q. You didn't know that every  
3 single over-the-counter product in America  
4 carries that same language?  
5 MS. JOHNSTON: Object to the  
6 form.  
7 THE WITNESS: I was not aware  
8 of that, but it certainly seems  
9 prudent.  
10 QUESTIONS BY MR. TRACEY:  
11 Q. All right. And that's true  
12 whether we're talking about cough drops,  
13 Tylenol or Gas-X, they all say exactly --  
14 they all say exactly the same thing.  
15 MS. JOHNSTON: Object to the  
16 form.  
17 QUESTIONS BY MR. TRACEY:  
18 Q. Did you know that?  
19 MS. JOHNSTON: Object to the  
20 form. Asked and answered.  
21 THE WITNESS: I shared with you  
22 I didn't know that, what all others --  
23 what all others have on their label.  
24 QUESTIONS BY MR. TRACEY:  
25 Q. All right. So you disagree

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1 that acetaminophen is often purchased over  
2 the counter and used for minor symptoms or  
3 discomfort where the treatment has no strong  
4 indication and carries little risk for the  
5 pregnant woman?  
6 MS. JOHNSTON: Object to the  
7 form.  
8 THE WITNESS: Well, what I  
9 would say is there's no reference for  
10 this here, and I don't know what data  
11 is used to support that statement.  
12 QUESTIONS BY MR. TRACEY:  
13 Q. Ma'am, have you ever taken  
14 Tylenol for a minor ache or pain?  
15 A. Usually, no.  
16 MS. JOHNSTON: Object to the  
17 form.  
18 THE WITNESS: I try -- usually,  
19 no. I try to avoid medication unless  
20 they're indicated.  
21 QUESTIONS BY MR. TRACEY:  
22 Q. Oh. Well, if Tylenol is  
23 indicated for minor aches or pains, is it  
24 okay to take it or no?  
25 MS. JOHNSTON: Object to the

<p style="text-align: right;">Page 290</p> <p>1 form.</p> <p>2 THE WITNESS: Well, if you're</p> <p>3 asking for me personally, it's fine to</p> <p>4 take it. I personally don't.</p> <p>5 In pregnancy, as I've stated,</p> <p>6 it should be a discussion with a</p> <p>7 health care professional and the</p> <p>8 patient.</p> <p>9 QUESTIONS BY MR. TRACEY:</p> <p>10 Q. What if you don't know you're</p> <p>11 pregnant, ma'am?</p> <p>12 MS. JOHNSTON: Object to form.</p> <p>13 THE WITNESS: Then how can we</p> <p>14 know what -- how can we know what to</p> <p>15 advise patients when they don't know</p> <p>16 if they're pregnant or not?</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. That's really, really a good</p> <p>19 point, isn't it?</p> <p>20 MS. JOHNSTON: Just wait for a</p> <p>21 question.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. Well, the point you just made,</p> <p>24 what do we advise if they don't know they're</p> <p>25 pregnant? That's a -- that's a good point</p>	<p style="text-align: right;">Page 292</p> <p>1 information to pregnant women that they would</p> <p>2 have to make their own decision about Tylenol</p> <p>3 with risks that are not well-identified in a</p> <p>4 label.</p> <p>5 And as I've stated many times,</p> <p>6 the tenet that we have in obstetrics for</p> <p>7 many, many years is -- and the standard of</p> <p>8 care -- is that a patient taking a medicine</p> <p>9 should not do that without contacting her</p> <p>10 health care professional.</p> <p>11 With respect to the risks of --</p> <p>12 to a woman of the -- notifying them of a</p> <p>13 potential -- or a reported association</p> <p>14 between ASD and ADHD, in my view it would</p> <p>15 cause very significant anxiety among patients</p> <p>16 who are pregnant.</p> <p>17 It may have negative</p> <p>18 consequences of them delaying therapy when</p> <p>19 it's indicated, and that has the potential of</p> <p>20 many, many other consequences of delaying</p> <p>21 therapy, especially for fever or severe pain</p> <p>22 that is not investigated.</p> <p>23 So I think the downside</p> <p>24 consequences for mothers of giving this</p> <p>25 fearful information, that, in my opinion, is</p>
<p style="text-align: right;">Page 291</p> <p>1 you're making, isn't it?</p> <p>2 MS. JOHNSTON: Object to the</p> <p>3 form.</p> <p>4 THE WITNESS: I don't know</p> <p>5 where -- what you mean by that. We</p> <p>6 can't advise patients if we don't know</p> <p>7 what's -- what the issues are.</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. Well, you could. You could put</p> <p>10 on a Tylenol label, "If you are pregnant or</p> <p>11 thinking of becoming pregnant, do not use</p> <p>12 unless the risk outweighs the benefit. Here</p> <p>13 are the risks," and you could list them,</p> <p>14 couldn't you?</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: You could do</p> <p>18 that, but in my opinion, that would</p> <p>19 have significant negative consequences</p> <p>20 for pregnant women.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. Okay. What negative</p> <p>23 consequences would it have if you were to put</p> <p>24 that language on a label for pregnant women?</p> <p>25 A. Well, number one, you're giving</p>	<p style="text-align: right;">Page 293</p> <p>1 not substantiated in the literature by the</p> <p>2 studies that are in existence at this point,</p> <p>3 would have enormous consequence for pregnant</p> <p>4 women all over the US.</p> <p>5 Q. Well, they would have enormous</p> <p>6 consequences for Johnson &amp; Johnson, too,</p> <p>7 wouldn't they?</p> <p>8 MS. JOHNSTON: Object to the</p> <p>9 form.</p> <p>10 THE WITNESS: Quite honestly,</p> <p>11 I'm not considering the consequences</p> <p>12 to Johnson &amp; Johnson.</p> <p>13 My role here today is to</p> <p>14 consider the consequences in treating</p> <p>15 a pregnant patient. I have not given</p> <p>16 any thought to what consequences would</p> <p>17 be for Johnson &amp; Johnson, and that's</p> <p>18 not for me.</p> <p>19 My role here is as a</p> <p>20 practitioner who sees so many pregnant</p> <p>21 patients, who deals with so many</p> <p>22 high-risk conditions, where there are</p> <p>23 so many cases of pain that can</p> <p>24 potentially be very serious for a</p> <p>25 mother or her baby, and so many -- so</p>

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1 many times where fever can have very  
 2 substantial risk to a mother and to  
 3 her baby, that that needs to be  
 4 carefully considered before putting  
 5 something in there that would scare a  
 6 pregnant women away from necessary  
 7 treatment.  
 8 MR. TRACEY: I'm going to  
 9 object to nonresponsive.  
 10 QUESTIONS BY MR. TRACEY:  
 11 Q. Doctor, you've testified a  
 12 hundred times, correct, or maybe more?  
 13 MS. JOHNSTON: Object to the  
 14 form.  
 15 THE WITNESS: I've gone through  
 16 that with you this morning.  
 17 QUESTIONS BY MR. TRACEY:  
 18 Q. Right?  
 19 A. I've told you -- I've shared  
 20 with you the number of depositions, and the  
 21 estimate of the number of depositions and the  
 22 number of --  
 23 Q. Yes, ma'am, that's why I asked  
 24 the question.  
 25 MS. JOHNSTON: Dr. D'Alton.

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1 Dr. D'Alton.  
 2 MR. TRACEY: You have testified  
 3 a hundred times or more?  
 4 MS. JOHNSTON: Dr. D'Alton, you  
 5 can finish your answer.  
 6 THE WITNESS: That's correct,  
 7 Mr. Tracey.  
 8 QUESTIONS BY MR. TRACEY:  
 9 Q. Okay. You have testified, you  
 10 told me, approximately 30 times live at  
 11 trial, correct?  
 12 A. Yes, I have.  
 13 Q. You have heard lawyers object  
 14 to your answers as being nonresponsive,  
 15 haven't you?  
 16 MS. JOHNSTON: Object to the  
 17 form.  
 18 THE WITNESS: Occasionally I've  
 19 heard that, but quite rarely,  
 20 Mr. Tracey. I try and answer the  
 21 question.  
 22 QUESTIONS BY MR. TRACEY:  
 23 Q. And you know exactly what it  
 24 means to be nonresponsive, Dr. D'Alton, don't  
 25 you?

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1 MS. JOHNSTON: Object to the  
 2 form.  
 3 THE WITNESS: No. My intent is  
 4 not to be nonresponsive, Mr. Tracey.  
 5 My intent, always, is to answer your  
 6 questions as honestly, as completely  
 7 and as forthrightly as I can.  
 8 QUESTIONS BY MR. TRACEY:  
 9 Q. My question was, Doctor, you  
 10 know what it means to be nonresponsive, don't  
 11 you?  
 12 MS. JOHNSTON: Object to the  
 13 form. Asked and answered.  
 14 THE WITNESS: I hope that I  
 15 would never be nonresponsive. I try  
 16 and be responsive in all of my  
 17 questions and do so in an appropriate  
 18 manner, in a forthright manner and in  
 19 as complete a manner as I can.  
 20 QUESTIONS BY MR. TRACEY:  
 21 Q. Doctor, do you think women are  
 22 incapable of evaluating medical evidence  
 23 coolly and calmly without becoming anxious or  
 24 scared?  
 25 MS. JOHNSTON: Object to the

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1 form.  
 2 THE WITNESS: I think it  
 3 depends on the woman and depends on  
 4 her background.  
 5 But I can tell you my own  
 6 experience in dealing with pregnant  
 7 women is that the anxiety level is  
 8 very substantial during pregnancy, and  
 9 women are very, very concerned about  
 10 possible effects on their baby. And  
 11 they -- we've seen -- we saw this very  
 12 much front and center during COVID.  
 13 And we are left, as obstetricians,  
 14 gynecologists and health care  
 15 providers, of dealing with that.  
 16 So this is a lot of information  
 17 to consider, and I think it would be  
 18 beyond the ability of many women to be  
 19 able to consider fully.  
 20 QUESTIONS BY MR. TRACEY:  
 21 Q. So we just don't tell them  
 22 anything?  
 23 MS. JOHNSTON: Object to the  
 24 form.  
 25 THE WITNESS: Mr. Tracey, I

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1 never said that, don't tell a woman  
2 anything. I've never said that. I've  
3 shared with you the importance of  
4 shared decision between a health care  
5 provider and her patient and how  
6 deeply and committedly obstetrician,  
7 gynecologist take that -- take that  
8 charge with their patient. They're  
9 advocates for their patients.

10 QUESTIONS BY MR. TRACEY:  
11 Q. Let me ask you this. If I had  
12 a bag of cough drops in my hand and I had a  
13 bottle of Tylenol in my hand, and they both  
14 said, "If you're pregnant, call your doctor."  
15 Are you with me?  
16 A. I'm trying to stay with you,  
17 Mr. Tracey, yes.  
18 Q. Are you there?  
19 A. I'm here.  
20 Q. Should I take away from this  
21 language that's on the bag of cough drops,  
22 that's on the bottle of Tylenol, that the  
23 risks are the same?  
24 MS. JOHNSTON: Object to the  
25 form. Incomplete hypothetical.

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1 THE WITNESS: So I'm  
2 actually -- I was with you until now,  
3 but I don't quite understand your last  
4 question, Mr. Tracey.

5 QUESTIONS BY MR. TRACEY:  
6 Q. What part?  
7 A. Oh, God, the full question.  
8 MS. JOHNSTON: That's fine.

9 QUESTIONS BY MR. TRACEY:  
10 Q. Okay. Do you expect women,  
11 pregnant women, to call you before they take  
12 a Hall's cough drop?  
13 MS. JOHNSTON: Object to the  
14 form.  
15 THE WITNESS: No, I don't,  
16 because a Hall's is not a medication.

17 QUESTIONS BY MR. TRACEY:  
18 Q. How about Gas-X?  
19 MS. JOHNSTON: Object to the  
20 form.  
21 THE WITNESS: Quite honestly,  
22 I'm not familiar about -- with Gas-X.  
23 I don't know -- I haven't heard of its  
24 use in pregnancy. I would have to  
25 look it up.

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1 QUESTIONS BY MR. TRACEY:  
2 Q. What about Dramamine, do you  
3 expect them to call you?  
4 MS. JOHNSTON: Same objection.  
5 THE WITNESS: I expect them to  
6 call me about drugs in pregnancy,  
7 about if they're taking  
8 over-the-counter medications in  
9 pregnancy, not about throat lozenges.

10 QUESTIONS BY MR. TRACEY:  
11 Q. Okay. So you don't know what  
12 Gas-X is?  
13 A. No.  
14 MS. JOHNSTON: Object to the  
15 form.  
16 THE WITNESS: I'd have to look  
17 it up, Mr. Tracey.  
18 MS. JOHNSTON: Let me just get  
19 my objection in there.  
20 THE WITNESS: Okay.

21 QUESTIONS BY MR. TRACEY:  
22 Q. What about Dramamine?  
23 MS. JOHNSTON: Same objection.  
24 THE WITNESS: Dramamine I would  
25 have to look up as well. I can't

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1 recall at this point the -- what  
2 Dramamine is.

3 QUESTIONS BY MR. TRACEY:  
4 Q. What about Pepto-Bismol?  
5 MS. JOHNSTON: Same objection.  
6 Outside the scope.  
7 THE WITNESS: Pepto-Bismol is  
8 something that is used for --  
9 frequently for diarrhea in pregnancy  
10 or diarrhea outside of pregnancy.

11 QUESTIONS BY MR. TRACEY:  
12 Q. It says on the bottle, "Call  
13 your doctor before using."  
14 Do you -- do you deal with a  
15 lot of Pepto-Bismol calls?  
16 MS. JOHNSTON: Object to the  
17 form.  
18 THE WITNESS: No, I deal with  
19 morely {sic} -- I mainly deal with  
20 symptoms, not related to Pepto-Bismol.  
21 So if I got a call about a  
22 symptom, then I would opine on that  
23 with a patient or I would discuss that  
24 with a patient and do the same  
25 risk/benefit analysis that I would do

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1 in a -- in a patient who is taking  
 2 Tylenol.  
 3 QUESTIONS BY MR. TRACEY:  
 4 Q. So would you expect your  
 5 patient, then, to call you before they took  
 6 Pepto-Bismol?  
 7 MS. JOHNSTON: Object to the  
 8 form.  
 9 THE WITNESS: Yes.  
 10 MS. JOHNSTON: Asked and  
 11 answered.  
 12 THE WITNESS: I would expect my  
 13 patients to call me about any new  
 14 medications that they are taking in  
 15 pregnancy.  
 16 My process is at the first  
 17 prenatal visit, I would go through all  
 18 of the existing drugs that they --  
 19 QUESTIONS BY MR. TRACEY:  
 20 Q. I didn't ask about your  
 21 process, ma'am.  
 22 MS. JOHNSTON: Dr. D'Alton, you  
 23 can certainly finish your answer to  
 24 the question --  
 25 MR. TRACEY: It's the

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1 non-responsive part to this.  
 2 MS. JOHNSTON: No, we're going  
 3 to -- we are going to --  
 4 MR. TRACEY: I asked about a  
 5 process.  
 6 MS. JOHNSTON: No. No. Sean,  
 7 we are going to stop this deposition  
 8 if this happens one more time.  
 9 Dr. D'Alton, finish --  
 10 MR. TRACEY: Stop it if you  
 11 want, but I -- I'm not going to listen  
 12 to her filibuster my time. That's not  
 13 what I asked her.  
 14 MS. JOHNSTON: Your question --  
 15 MR. TRACEY: Ask her what she's  
 16 answering.  
 17 MS. JOHNSTON: -- was about her  
 18 expectations for patients when they  
 19 are taking medications in pregnancy.  
 20 MR. TRACEY: No, it wasn't. It  
 21 was very specific about Pepto-Bismol.  
 22 MS. JOHNSTON: Your entire line  
 23 of questioning --  
 24 MR. TRACEY: And she's talking  
 25 about a process

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1 MS. JOHNSTON: You know what,  
 2 I'm actually not going to argue with  
 3 you either. And I don't appreciate  
 4 you interrupting me.  
 5 Here's what's going to happen.  
 6 Dr. D'Alton is going to finish her  
 7 answer to your questions or this  
 8 deposition ends. You and I can fight  
 9 all we want, but I will not allow you  
 10 to be disrespectful to Dr. D'Alton as  
 11 she's trying to answer the questions  
 12 that you're asking.  
 13 The fact that the questions are  
 14 absurd --  
 15 MR. TRACEY: Why don't you --  
 16 why don't you instruct Dr. D'Alton to  
 17 follow the rules of evidence and  
 18 answer the question that's asked?  
 19 MS. JOHNSTON: Sean --  
 20 MR. TRACEY: You want some time  
 21 to take her outside and explain to her  
 22 how this works and what's going to  
 23 happen in front of a judge?  
 24 MS. JOHNSTON: Sean, I would  
 25 love to take this in front of a judge

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1 right now, but you are not going to do  
 2 this any longer.  
 3 Dr. D'Alton is going to finish  
 4 her answers.  
 5 I'm not the one with the  
 6 problem here, Sean. Dr. D'Alton is  
 7 going to finish her answers.  
 8 MR. TRACEY: Look, look,  
 9 you-all create these controversies  
 10 that don't really exist because you  
 11 know there's a judge not here, and  
 12 you're trying to burn up our time.  
 13 I'm not playing that game with you.  
 14 I'm not doing it.  
 15 MS. JOHNSTON: Sean -- Sean, if  
 16 you want to burn up your time asking  
 17 questions about Pepto-Bismol, Gas-X  
 18 and a 60-page document from a  
 19 conference she attended, that's your  
 20 prerogative.  
 21 But she's going to answer her  
 22 questions -- the questions that you're  
 23 asking her, and she's going to  
 24 complete those answers.  
 25

<p style="text-align: right;">Page 306</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Let me ask --</p> <p>3 MS. JOHNSTON: If you interrupt</p> <p>4 her again, we are shutting this down.</p> <p>5 QUESTIONS BY MR. TRACEY:</p> <p>6 Q. Dr. D'Alton, do you expect your</p> <p>7 patients to call you before they take</p> <p>8 Pepto-Bismol?</p> <p>9 MS. JOHNSTON: Object to form.</p> <p>10 THE WITNESS: What I've tried</p> <p>11 to share with you, Mr. Tracey, is if</p> <p>12 they are taking Pepto-Bismol regularly</p> <p>13 and I know that from the first visit,</p> <p>14 I would not expect that they call me</p> <p>15 if I've gone through the -- the</p> <p>16 reasons why they're taking it.</p> <p>17 On the other hand, if they're</p> <p>18 planning to take a new medication in</p> <p>19 pregnancy, I would always ask those</p> <p>20 patients to call me prior to use so I</p> <p>21 could identify the symptomatology that</p> <p>22 they are using it for and understand</p> <p>23 if I need to see them in person for an</p> <p>24 evaluation.</p> <p>25</p>	<p style="text-align: right;">Page 308</p> <p>1 them to call you again is because the risk</p> <p>2 profile may have changed, true?</p> <p>3 MS. JOHNSTON: Object to the</p> <p>4 form.</p> <p>5 THE WITNESS: I mean, certainly</p> <p>6 that's a potential hypothetical, but</p> <p>7 with Tylenol, in my opinion, the risk</p> <p>8 profile has not changed.</p> <p>9 QUESTIONS BY MR. TRACEY:</p> <p>10 Q. Understood.</p> <p>11 But that is a reason why, for</p> <p>12 example, in 2012 there were not 23</p> <p>13 epidemiology studies looking at Tylenol and</p> <p>14 ADHD in autism, right?</p> <p>15 MS. JOHNSTON: Object to the</p> <p>16 form.</p> <p>17 THE WITNESS: That's correct.</p> <p>18 QUESTIONS BY MR. TRACEY:</p> <p>19 Q. And now there are?</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: There's a number</p> <p>23 of studies. I don't recall exactly</p> <p>24 how many. I'd have to look at them</p> <p>25 again.</p>
<p style="text-align: right;">Page 307</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. What if they took Tylenol with</p> <p>3 their first child after speaking with you and</p> <p>4 then they got pregnant again a couple years</p> <p>5 later, are they supposed to call you again?</p> <p>6 MS. JOHNSTON: Objection --</p> <p>7 THE WITNESS: Absolutely --</p> <p>8 MS. JOHNSTON: Object to the</p> <p>9 form.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: Absolutely they</p> <p>12 are expected to call me again,</p> <p>13 Mr. Tracey, because the indications</p> <p>14 for Tylenol use are myriad, and I want</p> <p>15 to be able to investigate whether</p> <p>16 that use is appropriate and whether I</p> <p>17 need to see the patient and whether I</p> <p>18 think that that symptomatology that</p> <p>19 they are considering using Tylenol for</p> <p>20 is something that I need to see them</p> <p>21 and evaluate them for before therapy.</p> <p>22 So, yes, Mr. Tracey, I would</p> <p>23 ask them to call me again before use.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. Another reason you might ask</p>	<p style="text-align: right;">Page 309</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Do you think that people like</p> <p>3 Dr. Liew and Dr. Baccarelli and other</p> <p>4 researchers like them should stop</p> <p>5 investigating Tylenol and neurodevelopmental</p> <p>6 disorders?</p> <p>7 MS. JOHNSTON: Object to the</p> <p>8 form.</p> <p>9 THE WITNESS: Absolutely not.</p> <p>10 Absolutely not. I do not believe</p> <p>11 that -- I would never call for an end</p> <p>12 to research. I would agree that</p> <p>13 research needs to continue and needs</p> <p>14 to be more precise and to be able to</p> <p>15 better answer the questions in front</p> <p>16 of us.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. Do you question</p> <p>19 Dr. Baccarelli's judgment?</p> <p>20 MS. JOHNSTON: Object to the</p> <p>21 form.</p> <p>22 THE WITNESS: I really don't</p> <p>23 know Dr. Baccarelli's judgment. I</p> <p>24 know his opinions, but judgment is</p> <p>25 something I think about in terms of --</p>

<p style="text-align: right;">Page 310</p> <p>1 what I'm usually familiar with in</p> <p>2 determining judgment is how they treat</p> <p>3 patients.</p> <p>4 How Dr. Baccarelli is in other</p> <p>5 formats, I can't comment on.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. If we continue to read Liew and</p> <p>8 Olsen, they say, "Not taking the drug under</p> <p>9 these conditions" -- which is the conditions</p> <p>10 where the minor symptoms or discomfort, where</p> <p>11 the treatment has no strong indication, they</p> <p>12 say, "Not taking the drug under these</p> <p>13 conditions will cause little harm, but taking</p> <p>14 the drug frequently might have health</p> <p>15 consequences for the unborn child."</p> <p>16 I assume you disagree with</p> <p>17 that?</p> <p>18 A. Yes, I do, because -- and for</p> <p>19 the reasons that I will share with you, that</p> <p>20 sometimes a minor symptom or a discomfort in</p> <p>21 pregnancy can be very substantial. And that</p> <p>22 needs to be investigated by an appropriate</p> <p>23 health care professional before it can be</p> <p>24 determined to be minor.</p> <p>25 The mother may think it's</p>	<p style="text-align: right;">Page 312</p> <p>1 Whether it's true generally,</p> <p>2 outside of pregnancy, I'm not going to</p> <p>3 speak about that. I'm here to talk</p> <p>4 about the evaluation of the symptoms</p> <p>5 and the importance of these symptoms</p> <p>6 in dealing with a pregnant person.</p> <p>7 Similarly headache in</p> <p>8 pregnancy. It may be mild, but if you</p> <p>9 have hypertension, that requires an</p> <p>10 evaluation. So there are many, many</p> <p>11 things in pregnancy that may come</p> <p>12 across as mild to the mother that when</p> <p>13 seen by a clinician may -- may be</p> <p>14 extremely important for that person's</p> <p>15 health and her baby's health.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. You don't prescribe Tylenol for</p> <p>18 headaches to pregnant women, do you?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: Well, of course I</p> <p>22 do. If there -- if they have</p> <p>23 headaches that needs to be treated, I,</p> <p>24 first of all, won't do it immediately.</p> <p>25 I will do an evaluation of the patient</p>
<p style="text-align: right;">Page 311</p> <p>1 minor, but it is an important evaluation that</p> <p>2 needs to be done by a health care</p> <p>3 professional to decide if, indeed, it is</p> <p>4 minor.</p> <p>5 Q. Okay. But what they say is not</p> <p>6 taking the drug under these conditions for</p> <p>7 minor symptoms or discomfort will cause</p> <p>8 little harm. That's a true statement,</p> <p>9 generally speaking. I understand there may</p> <p>10 be some exceptions.</p> <p>11 A. Well, I don't --</p> <p>12 MS. JOHNSTON: Object to the</p> <p>13 form.</p> <p>14 THE WITNESS: I'm sorry,</p> <p>15 Mr. Tracey, I would not agree with</p> <p>16 that at all in pregnancy because there</p> <p>17 are a myriad of conditions in</p> <p>18 pregnancy that have minor symptoms.</p> <p>19 And one of those is the treatment of</p> <p>20 preterm labor, is in the presentation</p> <p>21 of preterm labor. It may have very</p> <p>22 minor symptoms and the patient is</p> <p>23 already in advanced labor. So I would</p> <p>24 very much disagree with that in terms</p> <p>25 of pregnancy.</p>	<p style="text-align: right;">Page 313</p> <p>1 with headaches and determine with her</p> <p>2 what I believe the cause of the</p> <p>3 headache is or what the underlying</p> <p>4 cause of the headache could be and</p> <p>5 whether therapy is needed.</p> <p>6 QUESTIONS BY MR. TRACEY:</p> <p>7 Q. Your first-line treatment for</p> <p>8 headache is not Tylenol or any analgesic, is</p> <p>9 it?</p> <p>10 MS. JOHNSTON: Object to the</p> <p>11 form.</p> <p>12 THE WITNESS: Well, my</p> <p>13 first-line treatment is an evaluation</p> <p>14 of the cause for the headache. The</p> <p>15 cause for the headache could be as</p> <p>16 simple as caffeine withdrawal in early</p> <p>17 pregnancy as many women are concerned</p> <p>18 about the risks of caffeine, and from</p> <p>19 my experience clinically in dealing</p> <p>20 with pregnant patients in the first</p> <p>21 trimester, that is one of the reasons</p> <p>22 for -- common reasons for headache.</p> <p>23 So in that instance, I would</p> <p>24 more likely than not tell a patient to</p> <p>25 take some caffeine.</p>

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1 On the other hand, if a patient  
2 is telling me that she has not had  
3 anything to eat or drink all day, and  
4 in this heat that we've had this  
5 summer, one of the causes for headache  
6 could be that of dehydration. And how  
7 I would respond to headache in that  
8 fashion would be to treat the  
9 underlying cause, which is by giving  
10 them fluids.

11 So my therapy is not a  
12 generalized therapy, Mr. Tracey. It's  
13 an evaluation of what do I think the  
14 potential causes of the symptom and  
15 how they might be best addressed --  
16 best, first of all, evaluated and  
17 addressed by medication.

18 QUESTIONS BY MR. TRACEY:  
19 Q. Under what conditions do you  
20 tell your patients -- what types of headaches  
21 do you tell them to take Tylenol for?

22 MS. JOHNSTON: Object to the  
23 form.

24 THE WITNESS: Well, number one,  
25 I would tell them that after an

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1 evaluation of the symptomatology and  
2 make a decision, as I've said, about  
3 whether I would need to see the  
4 patient in person for an evaluation  
5 prior to giving -- prior to giving  
6 them that -- prior to recommending the  
7 medication.

8 So what kinds of patients would  
9 be patients where I don't think they  
10 need to be seen for flu-like symptoms,  
11 where I felt confident they were --  
12 did not have a low pulse ox, they  
13 didn't have a tachycardia, where they  
14 had flu symptoms with a fever, and  
15 then I would recommend Tylenol for  
16 that condition.

17 Then if the patient is having  
18 significant headaches and if the usual  
19 methods of rest and fluids and some  
20 caffeine are not controlling the  
21 headache, then I may recommend  
22 Tylenol.

23 So those are general  
24 indications that I would recommend  
25 Tylenol for

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1 With respect to treatment of  
2 acute migraine, I would use Tylenol.

3 Those are just a few of the  
4 indications that -- a few of the  
5 conditions that come to mind as for my  
6 indications for use of Tylenol.

7 QUESTIONS BY MR. TRACEY:  
8 Q. Would you warn them about what  
9 Dr. Liew and Olsen are concerned about or  
10 not?

11 MS. JOHNSTON: Object to the  
12 form.

13 THE WITNESS: Which part of  
14 what they're concerned about, so I can  
15 answer you specifically?

16 QUESTIONS BY MR. TRACEY:  
17 Q. Would you warn them that  
18 Dr. Liew and Olsen believe that Tylenol  
19 causes ADHD and ASD?

20 A. No --

21 MS. JOHNSTON: Same objection.

22 THE WITNESS: -- I would not.  
23 They're entitled to their opinion, and  
24 as I've shared with you multiple times  
25 today, my analysis of the literature

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1 is that there is significant  
2 methodologic flaws that does not allow  
3 me to make a causal link between  
4 prenatal use of acetaminophen and ADHD  
5 and ASD and does not change my  
6 clinical practice.

7 QUESTIONS BY MR. TRACEY:  
8 Q. And so I'm going to get back to  
9 where we started with that hours ago.

10 Is it your clinical practice  
11 that you only warn your patients about drug  
12 side effects if you have concluded they are  
13 causally related?

14 MS. JOHNSTON: Object to the  
15 form.

16 THE WITNESS: I think it  
17 depends on the evidence, and it  
18 depends on what is present in the --  
19 in the literature.

20 I mean, certainly I would need  
21 to have more specifics about that  
22 because there's a lot of drugs that  
23 are used in pregnancy, Mr. Tracey, and  
24 I would share with the -- the  
25 information with the patient in as

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1 best a way that I understood from my  
 2 evaluation of the data and from my  
 3 evaluation of the patient and the  
 4 indication for the -- for the  
 5 medicine.  
 6 QUESTIONS BY MR. TRACEY:  
 7 Q. Right.  
 8 But my question to you, Doctor,  
 9 is a little different than what you answered.  
 10 My question is, do you only  
 11 warn patients about side effects that a drug  
 12 may cause if you have concluded that they  
 13 are, in fact, causal?  
 14 MS. JOHNSTON: Object to the  
 15 form. Asked and answered.  
 16 THE WITNESS: Well, in coming  
 17 to my own conclusions, I would review  
 18 the literature, and I would also  
 19 review the body of evidence by our --  
 20 QUESTIONS BY MR. TRACEY:  
 21 Q. I heard all of that the first  
 22 time, Doctor.  
 23 A. Sorry. I didn't hear it --  
 24 Q. I heard all of that the first  
 25 time.

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1 A. Okay.  
 2 Q. I'm trying to get an answer to  
 3 my question.  
 4 MS. JOHNSTON: I think you've  
 5 got it twice or one and a half times.  
 6 MR. TRACEY: No, no, I haven't.  
 7 MS. JOHNSTON: Then I would ask  
 8 a different question because I'm  
 9 looking at this and she's answered it.  
 10 MR. TRACEY: No, no, I'm not  
 11 going to let the tactics dictate  
 12 different questions.  
 13 QUESTIONS BY MR. TRACEY:  
 14 Q. My question, Doctor, is, do you  
 15 only warn patients about drug side effects if  
 16 you have concluded there is causation?  
 17 MS. JOHNSTON: Same objections.  
 18 THE WITNESS: I think it  
 19 depends on what the drug is and what  
 20 my analysis has been -- has been. And  
 21 we're speaking today of Tylenol, and I  
 22 would need to know what drugs you're  
 23 talking about and to -- I'm not going  
 24 to answer that generally right now  
 25 because I don't have the information

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1 for all of the conditions that I might  
 2 treat or for all of the possible drugs  
 3 that I might use in pregnancy.  
 4 QUESTIONS BY MR. TRACEY:  
 5 Q. Have you ever seen the stress  
 6 in a mother who is trying to deal with a  
 7 severely autistic child?  
 8 MS. JOHNSTON: Object to the  
 9 form.  
 10 THE WITNESS: I absolutely have  
 11 seen that stress in a mother.  
 12 QUESTIONS BY MR. TRACEY:  
 13 Q. It's extraordinary, isn't it?  
 14 MS. JOHNSTON: Same objections.  
 15 THE WITNESS: The consequences  
 16 of dealing with a child with autism,  
 17 or with any child that has  
 18 disabilities, can be extraordinary for  
 19 a mother and a family.  
 20 QUESTIONS BY MR. TRACEY:  
 21 Q. That stress doesn't go away,  
 22 does it?  
 23 MS. JOHNSTON: Object to the  
 24 form.  
 25 THE WITNESS: You know, I don't

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1 look after children with autism or see  
 2 mothers long term. I see -- certainly  
 3 see some of my own patients who've had  
 4 a previous child with autism that come  
 5 to me for counseling that I refer to  
 6 genetics.  
 7 But seeing them long term and  
 8 seeing how their stress level changes  
 9 over time, I can't imagine that it  
 10 would go down, but I don't know the  
 11 answer to that.  
 12 QUESTIONS BY MR. TRACEY:  
 13 Q. On the last paragraph there on  
 14 the page, Drs. Liew and Olsen say, "Unlike  
 15 what is stated by the SMFM, we believe time  
 16 has come for some" --  
 17 A. Sorry, where -- I can't find  
 18 where you are. I apologize.  
 19 Q. If you look on the screen, you  
 20 can follow along.  
 21 A. Yeah. Okay. Well, it seems  
 22 that there's a delay because it wasn't being  
 23 highlighted when I asked you that, so I  
 24 apologize for interrupting you.  
 25 Q. They say, "Unlike what is

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1 stated by the SMFM, we believe time has come  
 2 for some precautionary action. Mothers-to-be  
 3 should at least be advised to avoid the drug  
 4 if treatment is not necessarily for her  
 5 conditions. If needed, careful use of the  
 6 drug and avoiding prolonged and/or high  
 7 frequency of exposures are some sensitive  
 8 advice that pregnant women should be given.  
 9 We hope the SMFM will revisit their  
 10 evaluation."  
 11 What do you think of that?  
 12 MS. JOHNSTON: Object to the  
 13 form.  
 14 THE WITNESS: I would disagree  
 15 that the time has come for  
 16 precautionary action.  
 17 What I would say is  
 18 precautionary action that they've  
 19 recommended is already done by  
 20 obstetrician, gynecologist and is no  
 21 change in practice. We always advise  
 22 patients not to take a drug unless it  
 23 is needed for her clinical conditions.  
 24 And if it is needed, to use for  
 25 the shortest possible time in the

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1 lowest possible dose.  
 2 So those -- that is sensitive  
 3 advice that is one of the foundational  
 4 tenets of our practice, and I did -- I  
 5 agree with that.  
 6 We hope that SMFM will revisit  
 7 their evaluation. So far SMFM has not  
 8 felt the need to revisit their  
 9 evaluation at this point. Whether  
 10 that's done in the near future, I  
 11 don't know that right now.  
 12 QUESTIONS BY MR. TRACEY:  
 13 Q. Have you ever recommended that  
 14 somebody take Tylenol for 30 days for a  
 15 condition?  
 16 MS. JOHNSTON: Object to the  
 17 form.  
 18 THE WITNESS: Yes, I have. I  
 19 have multiple patients that have had  
 20 very significant pain due to injury  
 21 and due to arthritis during pregnancy.  
 22 And the pain from that is  
 23 substantial, in those -- especially in  
 24 those two areas. Women can't sleep  
 25 because of the pain. Women sometimes

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1 are driven to distraction by the pain.  
 2 So I have recommended long-term  
 3 Tylenol use, and I continually -- I  
 4 continually reevaluate that at their  
 5 visit, but there's some patients that  
 6 need to take pain relief for more  
 7 prolonged periods of time, although  
 8 it's a very small number of patients  
 9 throughout pregnancy.  
 10 QUESTIONS BY MR. TRACEY:  
 11 Q. Have you ever delivered a child  
 12 that you later found out had autism?  
 13 MS. JOHNSTON: Object to the  
 14 form.  
 15 THE WITNESS: You know, I'm  
 16 sure that I have because I have had a  
 17 very large practice, and the incidence  
 18 of autism is of the order of 2 and a  
 19 half percent or so, so I have to have  
 20 delivered children who have had  
 21 autism.  
 22 QUESTIONS BY MR. TRACEY:  
 23 Q. Yeah. I mean, just  
 24 statistically speaking, you're saying you had  
 25 to have.

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1 What I'm wondering is, do you  
 2 ever see the children or the mothers later  
 3 after their autistic child has been  
 4 diagnosed?  
 5 MS. JOHNSTON: Object to the  
 6 form.  
 7 THE WITNESS: Sometimes I do.  
 8 QUESTIONS BY MR. TRACEY:  
 9 Q. Is it rare?  
 10 MS. JOHNSTON: Same objection.  
 11 THE WITNESS: Well, it depends  
 12 if they're having another pregnancy or  
 13 not, usually -- unless sometimes with  
 14 some of my patients where we develop a  
 15 very close relationship during the  
 16 pregnancy, they do want to see me  
 17 afterwards and come by my office to  
 18 say hello and tell me how they're  
 19 doing.  
 20 So I have some casual  
 21 conversations with some of my patients  
 22 because of the close bond that we  
 23 create during pregnancy.  
 24 And then many of my other  
 25 patients come back to have a repeat

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1 pregnancy with me.

2 QUESTIONS BY MR. TRACEY:

3 Q. Is it rare that you see a baby

4 that you delivered that has autism?

5 MS. JOHNSTON: Object to the

6 form. Asked and answered.

7 THE WITNESS: I wouldn't

8 usually see the baby unless the mother

9 brought the baby in with her, the

10 child in with her. I would usually

11 see the mother.

12 QUESTIONS BY MR. TRACEY:

13 Q. Yes. And my question is simply

14 this, is that a rare occurrence for you --

15 MS. JOHNSTON: Objection.

16 QUESTIONS BY MR. TRACEY:

17 Q. -- given your practice?

18 MS. JOHNSTON: Same objections.

19 THE WITNESS: You know, I can't

20 say I can give you data on it. I

21 don't know what you would consider

22 rare, but certainly it's probably less

23 than 2 or 3 percent of my practice.

24 (D'Alton Exhibit 918 marked for

25 identification.)

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1 QUESTIONS BY MR. TRACEY:

2 Q. Okay. Can we bring up, Ray,

3 Exhibit 918 and hand Dr. D'Alton a copy of

4 it? I think she's going to be familiar with

5 this.

6 Hold on. I've just been

7 corrected. Let me find it.

8 I meant to ask you about the

9 ACOG statement. We talked about the

10 Maternal-Fetal Medicine Society, and I

11 skipped ACOG. So I'm looking for it, Doctor.

12 A. Okay.

13 MS. JOHNSTON: We're setting

14 this one aside, Sean?

15 THE WITNESS: Yeah, please do.

16 MS. JOHNSTON: Sure.

17 MR. TRACEY: Here it is. It's

18 Exhibit 936B.

19 (D'Alton Exhibit 936B marked

20 for identification.)

21 QUESTIONS BY MR. TRACEY:

22 Q. Now, Doctor, you of course are

23 familiar with this statement that was put out

24 in September of 2021 in response to the

25 consensus?

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1 A. Yes, I am.

2 Q. And this is --

3 A. Can I just -- it's just --

4 they're just getting it for me, so just -- if

5 you would just give me a moment until I

6 can -- it can be delivered to me here.

7 Thanks very much. I appreciate

8 that.

9 I don't think this is it. This

10 is the consensus statement.

11 MS. JOHNSTON: What's the

12 number on this one?

13 MR. TRACEY: 936B.

14 MS. JOHNSTON: So it's 936B.

15 This is 936.

16 MR. TRACEY: Oh, sorry, my bad.

17 It's 936B.

18 VIDEOGRAPHER: I only see an A

19 and that one. There's no 936B.

20 THE WITNESS: I don't think

21 they have one, Mr. Tracey, but he's

22 looking.

23 QUESTIONS BY MR. TRACEY:

24 Q. Can you look at it on the

25 screen, ma'am? It's very short. It's less

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1 than a page.

2 VIDEOGRAPHER: There's no B.

3 THE WITNESS: I'll do my best.

4 QUESTIONS BY MR. TRACEY:

5 Q. Have the document -- do

6 whatever you need to do, but let's just

7 scroll. And here's my question.

8 Does the ACOG response to the

9 consensus statement cite one single study?

10 MS. JOHNSTON: Object to the

11 form.

12 THE WITNESS: It just cites the

13 response to Bauer.

14 MS. JOHNSTON: And I'll just

15 flag, too, that on the screen it's not

16 showing the entire statement.

17 MR. TRACEY: Yeah, there you

18 go.

19 THE WITNESS: Okay. Got it.

20 Thank you.

21 QUESTIONS BY MR. TRACEY:

22 Q. Do you see that they discuss

23 anything?

24 A. Sorry, I can't see it the way

25 it is right now. It's -- I can't see any of

Page 330

1 it.

2 RAY MOORE: I'll make it big,

3 and then I'll just scroll.

4 THE WITNESS: Okay. Thank you.

5 Oh, thanks very much.

6 MR. TRACEY: So just scroll for

7 Dr. D'Alton so she can see.

8 THE WITNESS: Thank you.

9 Do you mind to go a little bit

10 slower. Sorry?

11 RAY MOORE: No problem.

12 THE WITNESS: It's just I get

13 dizzy when you're going fast. I

14 apologize.

15 RAY MOORE: It's okay.

16 THE WITNESS: Okay. You can go

17 down now.

18 Yes.

19 QUESTIONS BY MR. TRACEY:

20 Q. They don't cite a single study,

21 do they?

22 A. They don't cite that here, no,

23 except that they're responding to Dr. Bauer

24 and her coauthors' statement.

25 Q. Do you know how many citations

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1 the Bauer consensus statement contains?

2 MS. JOHNSTON: Object to the

3 form.

4 THE WITNESS: I'd have to look

5 it up right now to tell you the exact

6 number.

7 MS. JOHNSTON: And, Sean, just

8 so you know, I'm handing Dr. D'Alton a

9 copy of the ACOG statement, just to

10 have it in front of her so we don't

11 have to scroll.

12 MR. TRACEY: Great.

13 QUESTIONS BY MR. TRACEY:

14 Q. You can confirm with me in a

15 second, but I count 165 different citations

16 in the consensus statement.

17 Does that sound right to you?

18 MS. JOHNSTON: Object to the

19 form.

20 THE WITNESS: There was a lot

21 of references in that. I can't -- it

22 sounds like a reasonable estimate, but

23 I don't have it in front of me,

24 Mr. Tracey.

25

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1 QUESTIONS BY MR. TRACEY:

2 Q. Do you recall the consensus

3 statement analyzing in vivo and in vitro

4 data?

5 MS. JOHNSTON: Object to the

6 form.

7 THE WITNESS: Yes.

8 QUESTIONS BY MR. TRACEY:

9 Q. Do you recall them looking at

10 animal models?

11 A. Yes.

12 MS. JOHNSTON: Same objection.

13 Let me just get my objection in

14 there.

15 QUESTIONS BY MR. TRACEY:

16 Q. Do you recall them looking at

17 in silico studies?

18 MS. JOHNSTON: Object to the

19 form.

20 THE WITNESS: I can't recall

21 that off the top of my head right now,

22 no.

23 QUESTIONS BY MR. TRACEY:

24 Q. Do you recall them evaluating

25 epidemiology?

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1 A. Yes.

2 Q. None of that is in the ACOG

3 one-page statement, true?

4 MS. JOHNSTON: Object to the

5 form.

6 THE WITNESS: That's correct,

7 none of those references are listed

8 here except the consensus statement

9 and where it was published.

10 QUESTIONS BY MR. TRACEY:

11 Q. And no authors of whoever wrote

12 this one-page response?

13 MS. JOHNSTON: Same objection.

14 THE WITNESS: That is correct.

15 QUESTIONS BY MR. TRACEY:

16 Q. Right?

17 A. That is correct.

18 Q. Do you know who wrote this?

19 A. No, I don't know who wrote

20 this.

21 Q. Could you find out if you asked

22 them? Do you think they would tell you?

23 MS. JOHNSTON: Same

24 objection -- or object to the form.

25 THE WITNESS: I can't speak for

<p style="text-align: right;">Page 334</p> <p>1 them, but I enjoy a close relationship</p> <p>2 with ACOG, and I believe they would</p> <p>3 tell me their process, but I have not</p> <p>4 tested that.</p> <p>5 QUESTIONS BY MR. TRACEY:</p> <p>6 Q. So the last paragraph said "the</p> <p>7 authors," but, again, we don't know who they</p> <p>8 are because they're not identified, right?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: That's correct.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. Okay. Now we'll go back to</p> <p>14 where I was.</p> <p>15 MS. JOHNSTON: 936?</p> <p>16 MR. TRACEY: Yes. Is that</p> <p>17 right?</p> <p>18 MS. JOHNSTON: That's the</p> <p>19 one --</p> <p>20 MR. TRACEY: No. Actually,</p> <p>21 yeah, if we just look -- look in the</p> <p>22 citations and just confirm for me that</p> <p>23 they cited 165 different papers.</p> <p>24 Ray, if you'd just go to the</p> <p>25 last page, you'll see that.</p>	<p style="text-align: right;">Page 336</p> <p>1 should be. Can you show me the front</p> <p>2 page of that? That's different than</p> <p>3 936. That's not my 936.</p> <p>4 MR. TRACEY: I don't know why</p> <p>5 it's wrong. This is why you do things</p> <p>6 in person. Yeah.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. I don't think there's going to</p> <p>9 be a significant argument over how many</p> <p>10 citations are in the paper, so I'm happy to</p> <p>11 move on, if we can't find it.</p> <p>12 Let's go back to Exhibit 918.</p> <p>13 This was the one that we had, Doctor, the</p> <p>14 ACOG Code of Professional Ethics.</p> <p>15 A. Got it. Sorry.</p> <p>16 Q. And you're familiar with the</p> <p>17 ACOG Code of Professional Ethics?</p> <p>18 A. I certainly have been familiar.</p> <p>19 I'm not sure when this was published. I see</p> <p>20 December 2018, but I am -- I haven't read it</p> <p>21 in a long time, so I'd need to familiarize</p> <p>22 myself with it.</p> <p>23 Q. There in the middle, you see I</p> <p>24 have highlighted "relationships with</p> <p>25 industry" and "expert testimony" at the top,</p>
<p style="text-align: right;">Page 335</p> <p>1 MS. JOHNSTON: You're asking</p> <p>2 her to look at Bauer 2021 and confirm</p> <p>3 the number of footnotes?</p> <p>4 MR. TRACEY: Yes.</p> <p>5 THE WITNESS: What I see is</p> <p>6 163.</p> <p>7 MR. TRACEY: Oh. Maybe my eyes</p> <p>8 are fading.</p> <p>9 MS. JOHNSTON: I'm sorry, I</p> <p>10 don't know what we're looking at right</p> <p>11 now.</p> <p>12 MR. TRACEY: Oh, you're right.</p> <p>13 163. You were right. I need better</p> <p>14 glasses.</p> <p>15 MS. JOHNSTON: Yeah, and --</p> <p>16 RAY MOORE: This is 936.</p> <p>17 MS. JOHNSTON: Yeah. We're</p> <p>18 looking at something different on the</p> <p>19 screen, Sean. That's what we're</p> <p>20 confused about.</p> <p>21 MR. TRACEY: Yeah. It should</p> <p>22 be 936. Actually, I don't know what</p> <p>23 that is on the screen. It's</p> <p>24 Exhibit 936.</p> <p>25 RAY MOORE: That's what it</p>	<p style="text-align: right;">Page 337</p> <p>1 right?</p> <p>2 Sorry, it's the middle -- I</p> <p>3 said the middle. That's not really. I meant</p> <p>4 the middle of the first paragraph.</p> <p>5 Do you see that?</p> <p>6 A. Could I just read that</p> <p>7 sentence? I see that that's what you're</p> <p>8 highlighting. I just want to read the</p> <p>9 context.</p> <p>10 Q. Yeah, I was going to read it.</p> <p>11 I was just going to orient.</p> <p>12 It says, "Certain documents the</p> <p>13 American College of Obstetricians and</p> <p>14 Gynecologists also provide additional ethical</p> <p>15 rules, including documents addressing the</p> <p>16 following issues: Seeking and giving</p> <p>17 consultation, informed consent, sexual</p> <p>18 misconduct, patient testing, relationships</p> <p>19 with industry, commercial enterprises in</p> <p>20 medical practice, and expert testimony."</p> <p>21 Are you familiar with those</p> <p>22 guidelines put out by the College?</p> <p>23 MS. JOHNSTON: Object to the</p> <p>24 form.</p> <p>25 THE WITNESS: You mean this</p>

<p style="text-align: right;">Page 338</p> <p>1 overall code of professional ethics or</p> <p>2 each one of these?</p> <p>3 I -- I'm not sure if they're</p> <p>4 alluding to -- they have bulletins on</p> <p>5 each one of those, I'm not familiar</p> <p>6 with that.</p> <p>7 <b>QUESTIONS BY MR. TRACEY:</b></p> <p>8 Q. Okay. Have you -- you have not</p> <p>9 reviewed the bulletins specific to</p> <p>10 relationships with industry?</p> <p>11 A. No, I have not.</p> <p>12 Q. Okay. Let's scroll down and</p> <p>13 look under number 1, Ethical Foundations.</p> <p>14 They say that, "The</p> <p>15 patient-physician relationship," and then</p> <p>16 they say, "The welfare of the patient,</p> <p>17 beneficence, is central to all considerations</p> <p>18 in the patient-physician relationship.</p> <p>19 "Included in this relationship</p> <p>20 is the obligation of physicians to respect</p> <p>21 the rights of patients, colleagues and other</p> <p>22 health professionals. The respect for the</p> <p>23 right of individual patients to make their</p> <p>24 own choices about their health care,</p> <p>25 autonomy, is fundamental."</p>	<p style="text-align: right;">Page 340</p> <p>1 recognize such situations and deal with them</p> <p>2 through public disclosure. Conflicts of</p> <p>3 interest should be resolved in accordance</p> <p>4 with the best interest of the patient,</p> <p>5 respecting a woman's autonomy to make health</p> <p>6 care decisions.</p> <p>7 "The physician should be an</p> <p>8 advocate for the patient through public</p> <p>9 disclosure of conflicts of interest raised by</p> <p>10 health payer policies or hospital policies."</p> <p>11 Do you agree with all that,</p> <p>12 ma'am?</p> <p>13 <b>MS. JOHNSTON:</b> Object to the</p> <p>14 form.</p> <p>15 <b>THE WITNESS:</b> Yes, I agree with</p> <p>16 avoiding conflicts of interest and</p> <p>17 disclosing conflicts of interest.</p> <p>18 <b>QUESTIONS BY MR. TRACEY:</b></p> <p>19 Q. Public disclosure?</p> <p>20 A. Public disclosure, yes.</p> <p>21 Q. Do you intend to publicly</p> <p>22 disclose your financial arrangements with the</p> <p>23 Johnson &amp; Johnson lawyers in this case to</p> <p>24 your patients?</p> <p>25 <b>MS. JOHNSTON:</b> Object to the</p>
<p style="text-align: right;">Page 339</p> <p>1 Do you agree with that last</p> <p>2 sentence?</p> <p>3 A. Yes.</p> <p>4 <b>MS. JOHNSTON:</b> Object to the</p> <p>5 form.</p> <p>6 <b>THE WITNESS:</b> Yes, I do.</p> <p>7 The patient respect is an</p> <p>8 important tenet in what we do.</p> <p>9 It's --</p> <p>10 <b>QUESTIONS BY MR. TRACEY:</b></p> <p>11 Q. In order for patients to make</p> <p>12 their own choices about their health care,</p> <p>13 they need to have information, don't they?</p> <p>14 <b>MS. JOHNSTON:</b> Object to the</p> <p>15 form.</p> <p>16 <b>THE WITNESS:</b> I would say, yes,</p> <p>17 they need to have information</p> <p>18 that's appropriate and that is clear.</p> <p>19 <b>QUESTIONS BY MR. TRACEY:</b></p> <p>20 Q. Under number III on Ethical</p> <p>21 Foundations, it says, "Avoiding conflicts of</p> <p>22 interest."</p> <p>23 It says, "Potential conflicts</p> <p>24 of interest are inherent in the practice of</p> <p>25 medicine. Physicians are expected to</p>	<p style="text-align: right;">Page 341</p> <p>1 form.</p> <p>2 <b>THE WITNESS:</b> I mean, I</p> <p>3 would -- I would certainly tell a</p> <p>4 patient if they asked me about Tylenol</p> <p>5 that I have knowledge in this because</p> <p>6 I've actually been an expert. So I</p> <p>7 would tell them that, yes.</p> <p>8 <b>QUESTIONS BY MR. TRACEY:</b></p> <p>9 Q. You said you would tell them</p> <p>10 that. I mean, that was kind of a convoluted</p> <p>11 answer. I'm asking something maybe a little</p> <p>12 different.</p> <p>13 Are you going to publicly</p> <p>14 disclose to your patients that you've been</p> <p>15 hired by the lawyers for Johnson &amp; Johnson?</p> <p>16 <b>MS. JOHNSTON:</b> Object to the</p> <p>17 form.</p> <p>18 <b>THE WITNESS:</b> I don't know how</p> <p>19 you mean "publicly disclosed." When I</p> <p>20 have disclosed previous conflicts of</p> <p>21 interest, I have written them as part</p> <p>22 of my disclosure policy when I publish</p> <p>23 an article, and that's public.</p> <p>24 I'm not a public person. I'm</p> <p>25 not out there, you know, telling</p>

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1 everybody that I'm on the board for  
 2 Merck for Mothers.  
 3 So it's -- when I give a talk  
 4 or when I publish a paper, I include  
 5 that I have received funding from  
 6 Merck for Mothers.  
 7 QUESTIONS BY MR. TRACEY:  
 8 Q. Is there anything in your  
 9 office that will tell patients that you  
 10 receive money from Merck for Mothers or  
 11 Johnson & Johnson?  
 12 MS. JOHNSTON: Object to the  
 13 form.  
 14 THE WITNESS: No. I have --  
 15 first of all, I have not received  
 16 money from Johnson & Johnson, as I've  
 17 disclosed to you today, as of this  
 18 present time. I have not sent an  
 19 invoice for my time.  
 20 When that happens, I will  
 21 disclose it, if I ever give a talk on  
 22 it.  
 23 I won't put -- I have not put a  
 24 sign in my office related to Merck for  
 25 Mothers or related to Johnson &

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1 Johnson. Certainly if asked about it,  
 2 I would be more than happy to be  
 3 transparent.  
 4 QUESTIONS BY MR. TRACEY:  
 5 Q. Okay. So do you think you  
 6 don't have a conflict now because you haven't  
 7 actually received money from Johnson &  
 8 Johnson lawyers?  
 9 MS. JOHNSTON: Object to the  
 10 form.  
 11 THE WITNESS: I certainly think  
 12 there could be a potential conflict,  
 13 but -- and it could be perceived as a  
 14 potential conflict. This has happened  
 15 pretty quickly over the last few  
 16 months that I've been engaged in this,  
 17 and honestly haven't given my  
 18 disclosure about this a great deal of  
 19 thought.  
 20 But it is never my intent to  
 21 hide public disclosure -- or to hide  
 22 disclosure to my patients, excuse me.  
 23 Public to me is when I write something  
 24 or when I speak about it.  
 25

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1 QUESTIONS BY MR. TRACEY:  
 2 Q. Does Columbia know about your  
 3 relationship with Johnson & Johnson's  
 4 lawyers?  
 5 MS. JOHNSTON: Object to the  
 6 form.  
 7 THE WITNESS: Not yet, but I  
 8 will disclose that to -- to them when  
 9 I update my conflict of interest  
 10 policy.  
 11 QUESTIONS BY MR. TRACEY:  
 12 Q. How often is that done?  
 13 A. It's done on a yearly basis.  
 14 Q. Okay. I have a -- you can take  
 15 that off the screen.  
 16 I'm going to show you  
 17 something.  
 18 MS. JOHNSTON: And, Sean, I'm  
 19 just going to flag that we're right  
 20 at -- I don't want to stop you if  
 21 you're on a roll, but we've been going  
 22 about another hour. So I just want to  
 23 get to a good stopping place for a  
 24 break. But if you want to keep going,  
 25 that's good.

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1 MR. TRACEY: Okay. Let me do  
 2 this quick setup and --  
 3 QUESTIONS BY MR. TRACEY:  
 4 Q. Doctor, I -- you'll be happy to  
 5 learn I bought one of your books. You're  
 6 going to get 30 cents in the next few months.  
 7 Can you see the book on the  
 8 screen that I'm holding up?  
 9 A. Oh, God, that's pretty old,  
 10 Mr. Tracey, as far as I remember. I don't  
 11 even recall that, but it's pretty old.  
 12 Q. It's 2007, I think.  
 13 A. Oh, yeah. So it's pretty  
 14 outdated right now.  
 15 Q. Yeah. And I'm not going to ask  
 16 you about anything in there except for one  
 17 sentence.  
 18 A. Got it.  
 19 Q. You and your coauthors start  
 20 out the book by saying -- sort of making the  
 21 point you just made, actually. "Because of  
 22 the dynamic nature of medical practice and  
 23 drug selection and dosage, users are advised  
 24 that decisions regarding drug therapy must be  
 25 based on the independent judgment of the

<p style="text-align: right;">Page 346</p> <p>1 clinician; changing information about a drug,  2 e.g., as reflected in the literature and  3 manufacturer's most current product  4 information; and changing medical practices."  5 That statement is all still  6 true, right?  7 A. You --  8 MS. JOHNSTON: You know, I'll  9 object to the form. I --  10 THE WITNESS: You know, there  11 was a lot in there.  12 MS. JOHNSTON: Yeah.  13 THE WITNESS: So it was hard to  14 follow. There was a lot of, you  15 know -- but thank you for showing me  16 it. I can't see it, actually, the way  17 you're showing it --  18 MS. JOHNSTON: Yeah.  19 THE WITNESS: -- Mr. Tracey --  20 I can see the highlighting, but then  21 most of it goes off the screen.  22 QUESTIONS BY MR. TRACEY:  23 Q. What's that?  24 A. Maybe if we took -- maybe if we  25 took the phrases one by one, I could go</p>	<p style="text-align: right;">Page 348</p> <p>1 That's still true?  2 A. Yes.  3 Q. And then the last thing you  4 said was, "And changing medical practices."  5 A. Yes, that's fair.  6 MR. TRACEY: Okay. All right.  7 Then let's take a break, and then  8 we'll come back.  9 THE WITNESS: Okay. Thank you.  10 VIDEOGRAPHER: The time right  11 now is 4 p.m. We are off the record.  12 (Off the record at 4:00 p.m.)  13 VIDEOGRAPHER: The time right  14 now is 4:20 p.m. We are back on the  15 record.  16 (D'Alton Exhibit 903 marked for  17 identification.)  18 QUESTIONS BY MR. TRACEY:  19 Q. Dr. D'Alton, I want to talk to  20 you about your report. It's -- I've got it  21 marked as Exhibit 903.  22 Do you have a copy in front of  23 you?  24 A. Yes. I can just --  25 MS. JOHNSTON: We should.</p>
<p style="text-align: right;">Page 347</p> <p>1 through it, but I couldn't -- I couldn't  2 focus enough to hear all of it. And I  3 apologize to you for asking you to do that  4 again.  5 Q. No, let's do it. It's not very  6 long.  7 A. Okay.  8 Q. "Because the dynamic nature of  9 medical practice and drug selection and  10 dosage, users are advised that decisions  11 regarding drug therapy must be based on," and  12 then you're going to list some things.  13 A. Got it.  14 Q. Okay?  15 A. Yeah, okay.  16 Q. Based on the independent  17 judgment of the clinician, that's one.  18 A. Yep.  19 Q. That's still true, right?  20 A. Oh, yes.  21 Q. Yeah.  22 "Changing information about a  23 drug, for example, as reflected in the  24 literature and manufacturer's most current  25 product information."</p>	<p style="text-align: right;">Page 349</p> <p>1 THE WITNESS: -- pull it.  2 MS. JOHNSTON: Yeah.  3 And you said 903, Sean?  4 MR. TRACEY: I don't need it  5 right now -- yeah.  6 Ray, I don't need it on the  7 screen right now. I just want  8 Dr. D'Alton to have a copy in front of  9 her.  10 QUESTIONS BY MR. TRACEY:  11 Q. Do you have it, Doctor?  12 A. I do.  13 Q. Now, can you point to me where  14 in your report you articulate the methodology  15 that you used to reach your opinions?  16 MS. JOHNSTON: And you can take  17 a look if you need to.  18 THE WITNESS: Can I just  19 quickly look?  20 It's under -- it's on page 5,  21 Materials Considered.  22 QUESTIONS BY MR. TRACEY:  23 Q. Okay. In that paragraph I'll  24 find your methodology?  25 A. Certainly that outlines the</p>

<p style="text-align: right;">Page 350</p> <p>1 methodology that I reviewed literature, 2 including some systematic reviews that were 3 conducted by ACOG and other relevant medical 4 bodies as well as epidemiology studies 5 related to acetaminophen in pregnancy. 6 Especially related to ASD and ADHD, 7 specifically related to those. 8 Q. Okay. Is -- okay. But I don't 9 actually -- are you saying that your 10 methodology consists of, "I have reviewed 11 literature, including systematic reviews 12 conducted by ACOG, SMFM and other relevant 13 medical bodies as well as epidemiology 14 studies pertaining to acetaminophen use in 15 pregnancy, and specifically the use of 16 acetaminophen in pregnancy and its 17 association with ASD and/or ADHD in 18 children"? 19 A. Yeah, I tried to review the 20 entire body of literature, epidemiologically, 21 that I found. Specifically related to when I 22 reviewed the Bauer report, I reviewed the -- 23 in that -- of those 163 citations that we 24 reviewed earlier, I reviewed the human 25 studies and the epidemiology studies related</p>	<p style="text-align: right;">Page 352</p> <p>1 form and to the extent it calls for a 2 legal conclusion. 3 THE WITNESS: Well, my 4 methodology is certainly related to my 5 review of the literature looking for 6 consistency, looking for replicated 7 data, looking for how confounders 8 were handled, looking for evidence of 9 dosage, looking for how the -- how ASD 10 and ADHD was diagnosed. 11 So I reviewed the articles 12 in -- as a clinician to review for 13 bias, for recall bias, for interview 14 bias, for confounders, for screening 15 versus diagnostic studies, and then 16 confounding by indication and 17 confounding by genetics. 18 So those were the -- dominantly 19 the areas that I considered. 20 QUESTIONS BY MR. TRACEY: 21 Q. Where do I find that in your 22 report, that that's what you set out to do? 23 MS. JOHNSTON: Object to the 24 form. 25 THE WITNESS: I'm not sure that</p>
<p style="text-align: right;">Page 351</p> <p>1 to ASD and ADHD. 2 I didn't pull all of the other 3 studies -- I didn't pull studies related to 4 animals because they are of no benefit in my 5 opinion and no impact on my opinion with 6 human pregnancy. 7 And I also reviewed many of the 8 commentaries that occurred after publication 9 of the Bauer 2021 study and the citations 10 that I felt were relevant in the back of 11 them. 12 I did a number of literature 13 reviews to look at treatment of pain in 14 pregnancy, treatment of migraine in 15 pregnancy, treatment of fever, acetaminophen 16 and ASD and ADHD, and gave in my report the 17 materials I considered. 18 Q. Right. 19 But my question -- I appreciate 20 all that. 21 On page 5 of your report, under 22 the Materials Considered list, is this your 23 articulated methodology that you employed in 24 this case to reach your opinions? 25 MS. JOHNSTON: Object to the</p>	<p style="text-align: right;">Page 353</p> <p>1 I said that out -- that I said that in 2 my report, but I did say what I 3 considered in terms of the weaknesses 4 of the epidemiologic research, and I 5 certainly mentioned Bauer and all of 6 the responses that -- maybe I haven't 7 mentioned all of the responses, but 8 many of the responses that have been 9 elucidated and have been published. 10 QUESTIONS BY MR. TRACEY: 11 Q. But Doctor -- Doctor, if you 12 wanted to recreate your work, and I wanted to 13 do what you did in order to see what you did, 14 where would I find that process, that 15 framework or that methodology in your report 16 to recreate? 17 MS. JOHNSTON: I'll object to 18 the form and say that the report 19 speaks for itself. 20 THE WITNESS: I mean, I haven't 21 detailed that I reviewed the 22 literature, but by process, I'm trying 23 to tell you today, I haven't been -- I 24 probably wasn't -- didn't go into 25 everything in this Materials</p>

<p style="text-align: right;">Page 354</p> <p>1 Considered except to provide for you</p> <p>2 with my report my list of Materials</p> <p>3 Considered.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. For example, you don't give a</p> <p>6 list of search terms that you used for what</p> <p>7 you were searching for?</p> <p>8 A. That's correct.</p> <p>9 Q. You don't give the hits that</p> <p>10 were returned and the various databases in</p> <p>11 terms of number of articles that met your</p> <p>12 search criteria?</p> <p>13 MS. JOHNSTON: Object to the</p> <p>14 form.</p> <p>15 THE WITNESS: No, I did not.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. We don't know what search terms</p> <p>18 you used because you don't tell us, correct?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: That's correct,</p> <p>22 in the report. I've shared with you</p> <p>23 in my last answer that I searched pain</p> <p>24 in pregnancy, fever in pregnancy,</p> <p>25 headache in pregnancy. All of the</p>	<p style="text-align: right;">Page 356</p> <p>1 that they're trying to answer?</p> <p>2 A. Yes. Most -- well, most</p> <p>3 applicable to this is the systematic review</p> <p>4 that was recently done and published by ACOG</p> <p>5 on headache in pregnancy and postpartum. So</p> <p>6 they detailed in that, like we discussed this</p> <p>7 morning --</p> <p>8 Q. Whoa, whoa, whoa, whoa. We're</p> <p>9 getting far afield, and I don't have a lot of</p> <p>10 time left.</p> <p>11 A. Okay.</p> <p>12 Q. My only question is, are you</p> <p>13 familiar with methodologies used in</p> <p>14 systematic reviews where they articulate the</p> <p>15 question that they're attempting to answer</p> <p>16 and the search criteria they used to identify</p> <p>17 relevant literature?</p> <p>18 A. I'm familiar with it, yes.</p> <p>19 Q. You did not do either one of</p> <p>20 those things in your report?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: No, I did not.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. Okay. You don't articulate the</p>
<p style="text-align: right;">Page 355</p> <p>1 things that would lead a practitioner</p> <p>2 to recommend Tylenol or acetaminophen</p> <p>3 use in pregnancy, and then I</p> <p>4 detailed -- also did a literature</p> <p>5 search on prenatal use of</p> <p>6 acetaminophen and ADHD and ASD.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. How do I confirm that your</p> <p>9 literature search was the right one; that is,</p> <p>10 how do I confirm what you did to see if you</p> <p>11 missed relevant literature?</p> <p>12 MS. JOHNSTON: Object to the</p> <p>13 form.</p> <p>14 THE WITNESS: Well, I think</p> <p>15 it's in my Materials Considered, and</p> <p>16 I, as a clinician, wanted to be as</p> <p>17 complete as possible, and I feel that</p> <p>18 I have determined that.</p> <p>19 Could I have missed something?</p> <p>20 I hope I did not miss anything</p> <p>21 important.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. Have you seen papers,</p> <p>24 systematic reviews, where they articulate</p> <p>25 that are search strategies and the question</p>	<p style="text-align: right;">Page 357</p> <p>1 question that you're being asked to answer in</p> <p>2 your report anywhere that I can find.</p> <p>3 Is that true?</p> <p>4 MS. JOHNSTON: Object to the</p> <p>5 form.</p> <p>6 THE WITNESS: I don't recall</p> <p>7 articulating the question. I think</p> <p>8 the -- my report is as it stands on</p> <p>9 the use of acetaminophen in pregnancy</p> <p>10 and its relationship to ASD and ADHD</p> <p>11 as I -- as I came up with in terms of</p> <p>12 being a clinician and a clinical</p> <p>13 investigator and an educator.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. So, for example, you didn't do</p> <p>16 a Bradford Hill analysis?</p> <p>17 A. No, I did not do that because I</p> <p>18 know that there is an epidemiologist that has</p> <p>19 been charged to do that.</p> <p>20 So my role here is as a</p> <p>21 clinician, as an educator and as someone who</p> <p>22 has considerable background in using Tylenol</p> <p>23 in pregnancy for patients throughout my</p> <p>24 career.</p> <p>25 Q. And is it fair to say that</p>

<p style="text-align: right;">Page 358</p> <p>1 there is no articulated methodology that you</p> <p>2 have identified in your report that anybody</p> <p>3 could go recreate? For example, if the judge</p> <p>4 wanted to recreate your methodology, it's</p> <p>5 nowhere to be found?</p> <p>6 MS. JOHNSTON: Object to the</p> <p>7 form. Asked and answered.</p> <p>8 THE WITNESS: Well, I've shared</p> <p>9 it with you this afternoon, what it</p> <p>10 is, what my -- what my review -- my</p> <p>11 review consisted of, and I think the</p> <p>12 Materials Considered are there to</p> <p>13 bolster that. And what I found in the</p> <p>14 literature, certainly the highlights</p> <p>15 of what I found in the literature and</p> <p>16 what I know from my clinical practice</p> <p>17 as a clinician and an educator, is</p> <p>18 detailed in the -- in the report.</p> <p>19 QUESTIONS BY MR. TRACEY:</p> <p>20 Q. What is -- you keep saying --</p> <p>21 let's see if I can find it.</p> <p>22 On the first page of your</p> <p>23 report in the last paragraph you say, "As</p> <p>24 described below and as informed by my</p> <p>25 clinical experience, an analysis of the body</p>	<p style="text-align: right;">Page 360</p> <p>1 form. Outside the scope.</p> <p>2 THE WITNESS: I don't know</p> <p>3 that, no.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. If I told you that the number</p> <p>6 one cause of accidental liver failure in the</p> <p>7 world, deaths from accidental liver failure</p> <p>8 in the world, was Tylenol, would that</p> <p>9 surprise you?</p> <p>10 MS. JOHNSTON: Same objections.</p> <p>11 THE WITNESS: It wouldn't</p> <p>12 surprise or not surprise me. If</p> <p>13 that's the case, that's the case. I</p> <p>14 know that Tylenol is toxic to the</p> <p>15 liver -- or overdose of Tylenol is</p> <p>16 toxic to the liver.</p> <p>17 QUESTIONS BY MR. TRACEY:</p> <p>18 Q. How much do you have to take in</p> <p>19 excess of the recommended daily dose to</p> <p>20 become toxic? Do you know?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form. Outside the scope.</p> <p>23 THE WITNESS: I think it varies</p> <p>24 depending on the publications that I</p> <p>25 have read. And my knowledge base is</p>
<p style="text-align: right;">Page 359</p> <p>1 of available literature, acetaminophen is an</p> <p>2 essential medication with a proven safety</p> <p>3 profile."</p> <p>4 Do you see that, ma'am?</p> <p>5 A. Yes.</p> <p>6 Q. Do you know what the number one</p> <p>7 cause of accidental liver failure deaths in</p> <p>8 the world is?</p> <p>9 MS. JOHNSTON: Object to the</p> <p>10 form.</p> <p>11 THE WITNESS: I don't know</p> <p>12 that, but I know that acetaminophen</p> <p>13 certainly has been reported to be</p> <p>14 associated -- to be a liver toxic</p> <p>15 agent, and it certainly has been</p> <p>16 reported in pregnancy when overdose --</p> <p>17 or large doses, certainly greater than</p> <p>18 12.5 milligrams and higher, have been</p> <p>19 used.</p> <p>20 QUESTIONS BY MR. TRACEY:</p> <p>21 Q. Do you know how long it took --</p> <p>22 after it was discovered that Tylenol was</p> <p>23 toxic to the liver, how long it took before a</p> <p>24 warning was put on the bottle?</p> <p>25 MS. JOHNSTON: Object to the</p>	<p style="text-align: right;">Page 361</p> <p>1 only in pregnancy. And what I've seen</p> <p>2 in pregnancy is that it's anywhere</p> <p>3 north of 24 milligrams to</p> <p>4 50 milligrams. So -- sorry, 50 grams.</p> <p>5 Sorry. Of Tylenol. So 24 to 50 is</p> <p>6 what I've seen in the literature.</p> <p>7 There may be others that are a</p> <p>8 little different, but there's a</p> <p>9 variation in the number that is -- has</p> <p>10 been associated with liver toxicity.</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Are you saying you think that</p> <p>13 the overdose threshold is 24 grams a day?</p> <p>14 MS. JOHNSTON: Object to the</p> <p>15 form.</p> <p>16 THE WITNESS: As best I can</p> <p>17 recollect from the literature, that's</p> <p>18 what has been reported in pregnancy.</p> <p>19 And there may be ones that are less</p> <p>20 than that, but the ones that stand out</p> <p>21 in my mind are very substantial doses</p> <p>22 of acetaminophen that have been taken</p> <p>23 in a very short period of time. One</p> <p>24 report, in fact, up to 50 grams.</p> <p>25</p>

<p style="text-align: right;">Page 362</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Are you talking about case</p> <p>3 reports or actual epidemiology?</p> <p>4 MS. JOHNSTON: Object to the</p> <p>5 form. Outside the scope.</p> <p>6 THE WITNESS: I'm talking about</p> <p>7 case reports on the use of -- and I</p> <p>8 believe there's a collection of data</p> <p>9 that has been reported on the use of</p> <p>10 acetaminophen in pregnancy and its</p> <p>11 effects on the liver, on the maternal</p> <p>12 liver.</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. Is it your belief that it's</p> <p>15 widely understood in the medical community</p> <p>16 that Tylenol is capable of liver toxicity?</p> <p>17 MS. JOHNSTON: Object to the</p> <p>18 form.</p> <p>19 THE WITNESS: I think that's</p> <p>20 widely known to obstetrician,</p> <p>21 gynecologists, for sure.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. Okay. Do you recall a time --</p> <p>24 you know there's a box warning on Tylenol for</p> <p>25 liver failure, liver toxicity?</p>	<p style="text-align: right;">Page 364</p> <p>1 Is there any method -- does</p> <p>2 your methodology have a name that I can go</p> <p>3 look up and pull in the literature and show</p> <p>4 the judge?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form.</p> <p>7 THE WITNESS: Well, my</p> <p>8 methodology is to go through the</p> <p>9 published literature -- it doesn't</p> <p>10 have a name. My methodology is being</p> <p>11 knowledgeable of the system -- of the</p> <p>12 grading system that's used by ACOG in</p> <p>13 their systematic reviews and my</p> <p>14 knowledge base as a clinician in</p> <p>15 reviewing clinical evidence and</p> <p>16 epidemiologic data for consistency for</p> <p>17 evidence of replication, for evidence</p> <p>18 of bias, for evidence of confounders</p> <p>19 or failure to control for confounders</p> <p>20 and limitations of a study in relation</p> <p>21 to genetic confounders.</p> <p>22 So that was my process in</p> <p>23 evaluating the literature.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. What's the name of the ACOG</p>
<p style="text-align: right;">Page 363</p> <p>1 MS. JOHNSTON: Object to the</p> <p>2 form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 QUESTIONS BY MR. TRACEY:</p> <p>5 Q. Okay. Do you know how long</p> <p>6 that warning has been on the bottle?</p> <p>7 A. No.</p> <p>8 MS. JOHNSTON: Same objections.</p> <p>9 THE WITNESS: I don't know that</p> <p>10 at this point.</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Okay. Back to -- back to</p> <p>13 your methodology.</p> <p>14 Is there a name for the</p> <p>15 methodology you employed that I can go look</p> <p>16 up -- look up in the medical literature like,</p> <p>17 you know -- I'm just going to throw some</p> <p>18 names out for you to sort of inspire you if</p> <p>19 there is one.</p> <p>20 We have Bradford Hill. We have</p> <p>21 Adverse Outcome Pathways. We have something</p> <p>22 called the Navigation Guide. We have</p> <p>23 something called the GRADE system by the</p> <p>24 Cochrane Collaboration, things of that</p> <p>25 nature.</p>	<p style="text-align: right;">Page 365</p> <p>1 grading system for systematic analysis you</p> <p>2 just referenced?</p> <p>3 A. It's GRADE.</p> <p>4 Q. G-R-A-D-E?</p> <p>5 A. Yes.</p> <p>6 Q. That's what ACOG use?</p> <p>7 A. That is what it has used. It</p> <p>8 has a published methodology and what they use</p> <p>9 for clinical practice guidelines, and they</p> <p>10 use GRADE.</p> <p>11 And then they use levels of</p> <p>12 evidence to share that information with</p> <p>13 clinicians for how strong or not strong</p> <p>14 they -- the levels of evidence are for that</p> <p>15 particular recommendation.</p> <p>16 Q. And you made no effort to grade</p> <p>17 the evidence in your report in any methodical</p> <p>18 way using an a priori scoring system?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: No, I didn't do</p> <p>22 that in my report because I was</p> <p>23 knowledgeable that an epidemiologist</p> <p>24 was doing that, and that was -- that</p> <p>25 was not something that I, as a</p>

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1 clinician, needed to weigh in on.

2 I was asked as a clinician to

3 provide a clinical lens on the issue

4 of Tylenol use in pregnancy and as a

5 clinician educator, my analysis of the

6 literature, being knowledgeable about

7 what obstetrician, gynecologists are

8 thinking and their societies and their

9 professional bodies are thinking about

10 this around the world as to the

11 causative link between prenatal use of

12 acetaminophen and AH -- ADHD and ASD.

13 MR. TRACEY: I'm going to

14 object to nonresponsive.

15 QUESTIONS BY MR. TRACEY:

16 Q. You have articulated no grading

17 system in your report where you even

18 attempted to develop and use an a priori

19 system to evaluate the literature?

20 A. I did not do that, no. I've

21 stated that for you today.

22 Q. And you did not evaluate any of

23 the animal literature, correct?

24 A. No. My knowledge base is not

25 in animal research, and it is my opinion that

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1 animal research on Tylenol does not impact my

2 clinical opinion.

3 Q. Well, how would you know that

4 if you haven't read any of it?

5 A. Because --

6 MS. JOHNSTON: Object to the

7 form.

8 THE WITNESS: Because of what I

9 know about animal research related to

10 other drugs, that it has no impact on

11 the clinical opinion when there's

12 human data.

13 QUESTIONS BY MR. TRACEY:

14 Q. Do you know whether animal

15 studies suffer from confounding?

16 MS. JOHNSTON: Object to the

17 form.

18 THE WITNESS: As I've shared

19 with you, I haven't reviewed any of

20 the animal studies. Usually they're

21 there for hypothesis-generating,

22 mechanistic evidence, but it is not my

23 expertise, and I will not comment on

24 it.

25

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1 QUESTIONS BY MR. TRACEY:

2 Q. Did you know that the FDA right

3 here, right now is undertaking an animal

4 study to answer the question of causation in

5 Tylenol and neurodevelopmental disorders?

6 MS. JOHNSTON: Object to the

7 form.

8 THE WITNESS: I was not aware

9 of the FDA's doing this in animal

10 models, but I would say to you as a

11 clinician, that would not be enough

12 evidence to rely on the information

13 that would be required in -- for

14 clinical studies, for clinical

15 practice.

16 MR. TRACEY: Okay. I'm going

17 to object to nonresponsive.

18 QUESTIONS BY MR. TRACEY:

19 Q. But you were unaware that that

20 is exactly what the FDA is doing now?

21 MS. JOHNSTON: Object to the

22 form.

23 THE WITNESS: I was not aware

24 of that, no.

25

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1 QUESTIONS BY MR. TRACEY:

2 Q. Okay. The question I asked you

3 was about confounding in animal studies.

4 The reason I asked it is

5 because you volunteered that you have

6 knowledge of animal studies with other drugs.

7 Did I hear that correctly or

8 no?

9 A. Well, I know they've been done

10 with other drugs, but clinically, the use of

11 animal studies is not usually relevant in a

12 clinical recommendation for a drug. It's

13 based on human data.

14 Q. Do you know whether any

15 clinical trials were done with Tylenol before

16 it began being sold in America?

17 MS. JOHNSTON: Object to the

18 form.

19 THE WITNESS: No, I am not.

20 It's been around for a very long time.

21 I believe it was approved somewhere in

22 the '50s, and I am not aware of what

23 studies were done prior to its

24 introduction.

25

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1 QUESTIONS BY MR. TRACEY:

2 Q. Do you know whether or not

3 neurodevelopmental testing is required now by

4 the FDA before a drug can enter the market?

5 A. No. I'm not an expert on when

6 drugs can enter the market and requirements

7 therein. I am a clinician who practices

8 obstetrics and gynecology -- that practices

9 obstetrics, actually, and maternal-fetal

10 medicine, and I'm here as a clinician and an

11 educator.

12 Q. Doctor, has anyone explained to

13 you that we're in phase I of this case, that

14 phase I is about whether or not Tylenol is

15 capable of causing ADHD or ASD, and there's

16 really no risk/benefit analysis being done at

17 this point in the literature?

18 Did you know that?

19 MS. JOHNSTON: And I'll just

20 object and remind Dr. D'Alton that I'm

21 sure Mr. Tracey is not asking her to

22 disclose any conversations she's had

23 with attorneys.

24 MR. TRACEY: No, I'm not.

25 MS. JOHNSTON: So outside of

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1 that --

2 MR. TRACEY: I'm not.

3 MS. JOHNSTON: Dr. D'Alton.

4 QUESTIONS BY MR. TRACEY:

5 Q. But I'm trying to understand

6 what you know and what you think we're doing

7 in this part of the litigation.

8 MS. JOHNSTON: And I would give

9 the same instruction.

10 THE WITNESS: I'm not sure I've

11 ever heard the term "phase I of the

12 litigation." So I'm not sure what

13 that is, Mr. Tracey.

14 QUESTIONS BY MR. TRACEY:

15 Q. Yeah. That's what I -- that's

16 what I thought, to tell you the truth.

17 Have you seen the order from

18 the judge about what phase I means in this

19 case?

20 MS. JOHNSTON: Same objections.

21 THE WITNESS: I can't recall if

22 I have or not at this point. I don't

23 recall it at the present time.

24 QUESTIONS BY MR. TRACEY:

25 Q. Okay. All right.

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1 Oh, did you know that your

2 university has an animal model lab to look

3 at in animal -- in mouse models whether or

4 not drugs or environmental toxins are capable

5 of causing neurodevelopmental disorders?

6 MS. JOHNSTON: Object to the

7 form.

8 THE WITNESS: It wouldn't

9 surprise me. There's a vast amount of

10 research being done at Columbia, and

11 we have some basic science in our

12 departments.

13 So I know that research is a

14 major priority for Columbia University

15 and for its investigators. And

16 developmental delay is a very

17 important issue, and it would not

18 surprise me that basic science is

19 being actively conducted at Columbia

20 University.

21 QUESTIONS BY MR. TRACEY:

22 Q. Okay. Do you know where the

23 mouse -- where the mouse laboratory is? Have

24 you -- do you know where it is physically?

25 A. I know there's a number of

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1 mouse labs, and there isn't enough labs to

2 house all of the mice or the mice across

3 the university.

4 So it's always a bit of an

5 issue as to where the mice can be housed at

6 Columbia University because of the space

7 requirements.

8 Q. Okay. Before the break, you

9 and I read this first sentence out of your

10 now-dated book, Maternal-Fetal Medicine.

11 And it talked about the fact

12 that things change and you need to keep

13 abreast of changing information as reflected

14 in the literature and manufacturer's most

15 current product information.

16 Do you remember that brief

17 conversation we had?

18 A. I do.

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

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<div>Page 374</div> <div>[REDACTED]</div>	<div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>

[illegible]

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<div>Page 382</div> <div>[REDACTED]</div>	<div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>

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<p>Page 386</p> <p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

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(D'Alton Exhibit 915A marked for identification.)

QUESTIONS BY MR. TRACEY:

Q. Okay. 915A is the next exhibit.

This, ma'am, is the -- is the Cadence product label that they referenced under Preclinical under 162. At the top you'll see it says --

MS. JOHNSTON: Hey, Sean, we're just waiting on a copy.

THE WITNESS: I don't have it. Sorry.

MR. TRACEY: Sorry. I can't -- I can only see me in the screen, and I can't see you guys right now.

MS. JOHNSTON: No problem. We got it. We're getting our copies.

And sorry, which one was this?

MR. TRACEY: This is the Cadence Pharmaceutical document that we referenced.

MS. JOHNSTON: 915A?

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MR. TRACEY: Yeah, 915A. Sorry.

MS. JOHNSTON: Thank you.

QUESTIONS BY MR. TRACEY:

Q. Now, if you'll see there, it says, "These highlights do not include all the information needed to use Ofirmev safely and effectively. See full prescribing information."

Do you see that, ma'am?

A. I do.

Q. Now, I want to flip over -- oh, by the way, this has -- flip over to the Section 8.1, Pregnancy and, unfortunately, these aren't numbered, so you kind of -- so, Ray, you've got to flip through until you get to Pregnancy, 8.1.

Do you see that it says that this is a Pregnancy Category C?

A. I think it's related to IV acetaminophen.

Q. We're going to get there, ma'am, but, yes.

A. Okay.

Q. We're going to get there.

<p style="text-align: right;">Page 394</p> <p>1 This product is an IV</p> <p>2 acetaminophen that is what J&amp;J referenced in</p> <p>3 support of their claim to no teratogenicity.</p> <p>4 Okay?</p> <p>5 MS. JOHNSTON: Just object to</p> <p>6 the form.</p> <p>7 QUESTIONS BY MR. TRACEY:</p> <p>8 Q. They say, "Pregnancy</p> <p>9 Category C. There are no studies of</p> <p>10 intravenous acetaminophen in pregnant women;</p> <p>11 however, epidemiological data on oral</p> <p>12 acetaminophen use in pregnant women showed no</p> <p>13 increased risk of major congenital</p> <p>14 malformations. Animal reproduction studies</p> <p>15 have not been conducted with IV</p> <p>16 acetaminophen, and it is not known whether</p> <p>17 Ofirmev can cause fetal harm when</p> <p>18 administered to pregnant women. Ofirmev</p> <p>19 should be given to pregnant women only if</p> <p>20 clearly needed."</p> <p>21 Do you see that, ma'am?</p> <p>22 A. I do.</p> <p>23 Q. And then we're going to flip</p> <p>24 over to the next page and see what the data</p> <p>25 is that they use to reach that conclusion.</p>	<p style="text-align: right;">Page 396</p> <p>1 acetaminophen?</p> <p>2 MS. JOHNSTON: Objection.</p> <p>3 Form.</p> <p>4 THE WITNESS: Well, these are</p> <p>5 studies that have been done in animal</p> <p>6 studies. So, quite honestly, I think</p> <p>7 a doctor would probably not make</p> <p>8 decisions based on animal studies</p> <p>9 showing reduced fetal weight and</p> <p>10 length and dose-related increase in</p> <p>11 bone variation in terms of considering</p> <p>12 this for use in pregnancy. It should</p> <p>13 only have been used when indicated.</p> <p>14 QUESTIONS BY MR. TRACEY:</p> <p>15 Q. Well, let's be clear, though,</p> <p>16 ma'am. This is under a pregnancy rating</p> <p>17 category, and this information is required to</p> <p>18 be put in the label, correct?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form.</p> <p>21 THE WITNESS: As I said to you,</p> <p>22 I'm not a labeling expert, and I don't</p> <p>23 know what's required to put in the</p> <p>24 label.</p> <p>25</p>
<p style="text-align: right;">Page 395</p> <p>1 Okay?</p> <p>2 A. Okay.</p> <p>3 Q. It says, "While animal</p> <p>4 reproduction studies have not been conducted</p> <p>5 with intravenous acetaminophen, studies in</p> <p>6 pregnant rats that received oral</p> <p>7 acetaminophen during organogenesis at doses</p> <p>8 up to .85 times the maximum human daily dose,</p> <p>9 showed evidence of fetotoxicity and a</p> <p>10 dose-related increase in bone variations,</p> <p>11 reduced ossification and rudimentary rib</p> <p>12 changes."</p> <p>13 Do you see that?</p> <p>14 A. I do.</p> <p>15 Q. Do you know what fetotoxicity</p> <p>16 is, ma'am?</p> <p>17 MS. JOHNSTON: Object to the</p> <p>18 form.</p> <p>19 THE WITNESS: Yes, toxic to the</p> <p>20 fetus.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. Yes.</p> <p>23 Is that something that you</p> <p>24 think a doctor might want to know when they</p> <p>25 were deciding whether or not to prescribe</p>	<p style="text-align: right;">Page 397</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. No, ma'am, but you're a</p> <p>3 maternal-fetal medicine expert who knows or</p> <p>4 should know pregnancy labeling categories,</p> <p>5 aren't you?</p> <p>6 MS. JOHNSTON: Object to the</p> <p>7 form.</p> <p>8 THE WITNESS: Well, I think the</p> <p>9 labeling categories have gone now.</p> <p>10 They're not being used anymore. So</p> <p>11 that is not being used anymore, to my</p> <p>12 knowledge.</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. No, ma'am, we're going to get</p> <p>15 to the latest and greatest in just a minute,</p> <p>16 but we have to take these things one at a</p> <p>17 time.</p> <p>18 Do you understand that</p> <p>19 Category C means there is evidence of fetal</p> <p>20 risk in animal studies?</p> <p>21 MS. JOHNSTON: Object to the</p> <p>22 form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 QUESTIONS BY MR. TRACEY:</p> <p>25 Q. And during the pregnancy</p>

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1 labeling category regime, it was required to  
 2 tell prescribers whether there was evidence  
 3 of fetal harm in animal studies, correct?  
 4 MS. JOHNSTON: Object to the  
 5 form.  
 6 THE WITNESS: As best as you've  
 7 gone through all of these documents  
 8 today, as I shared in the beginning of  
 9 review of these documents, I haven't  
 10 seen these before, and to answer them  
 11 carefully and appropriately, I would  
 12 need to restudy them, and it's not my  
 13 practice or my expertise.  
 14 So it's difficult for me to  
 15 answer these questions for you,  
 16 Mr. Tracey.  
 17 QUESTIONS BY MR. TRACEY:  
 18 Q. Well, that question I just  
 19 asked you had nothing to do with these  
 20 documents. It had to do with the pregnancy  
 21 categories.  
 22 MS. JOHNSTON: Wait for a  
 23 question.  
 24 QUESTIONS BY MR. TRACEY:  
 25 Q. Do you remember my question, or

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1 do I need to ask it again?  
 2 A. Sure, if you would ask it again  
 3 because I don't recall your question at this  
 4 point.  
 5 Q. You knew and understood when  
 6 the pregnancy categories were being used that  
 7 Category C meant that there was -- there was  
 8 evidence of harm to the fetus in animal  
 9 studies, right?  
 10 MS. JOHNSTON: Object to the  
 11 form.  
 12 THE WITNESS: Yes, I knew that  
 13 when we were dealing with the  
 14 categories.  
 15 QUESTIONS BY MR. TRACEY:  
 16 Q. And you knew that it -- that  
 17 information had to be contained, had to be  
 18 put on a product label for a doctor or  
 19 anybody else to see.  
 20 MS. JOHNSTON: Object to the  
 21 form.  
 22 QUESTIONS BY MR. TRACEY:  
 23 Q. Right?  
 24 A. Yeah, that is -- I can't  
 25 remember what I knew then about it in 2000 --

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1 I believe it was 2015 when those stopped,  
 2 when the -- when we stopped using the  
 3 categories.  
 4 So I don't remember what was  
 5 required to put in the information for  
 6 practicing health care professionals who  
 7 would prescribe intravenous -- intravenous  
 8 acetaminophen.  
 9 Q. And just to state the obvious,  
 10 Doctor, Tylenol, of course, has been  
 11 available over the counter for 60 years,  
 12 right?  
 13 MS. JOHNSTON: Object to the  
 14 form.  
 15 THE WITNESS: Yes, but we're --  
 16 I understand that we're talking now  
 17 about IV acetaminophen, which has not  
 18 been available for all that length.  
 19 QUESTIONS BY MR. TRACEY:  
 20 Q. No, ma'am.  
 21 But the data that they're  
 22 basing this category on --  
 23 (Audio interruption.)  
 24 Q. This label goes on to say,  
 25 "When pregnant" -- "pregnant rats received

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1 oral acetaminophen throughout gestation at  
 2 doses of 1.2 times the maximum human daily  
 3 dose, based on body surface area comparison,  
 4 areas of necrosis occurred in both the liver  
 5 and kidney of pregnant rats and fetus. These  
 6 effects did not occur in animals that  
 7 received oral acetaminophen at doses .3 times  
 8 the maximum human daily dose based on body  
 9 surface area comparison."  
 10 Do you understand that to be a  
 11 dose-response there, Doctor?  
 12 MS. JOHNSTON: Object to form.  
 13 THE WITNESS: I would need to  
 14 look at the full article to be able to  
 15 assess that, whether that's a  
 16 dose-response or not.  
 17 QUESTIONS BY MR. TRACEY:  
 18 Q. Okay. They go on to say, "In a  
 19 continuous breeding study, pregnant mice  
 20 received .25, .5 or 1 percent acetaminophen  
 21 via the diet," and they have the mgs per kgs  
 22 per day.  
 23 "These doses are  
 24 approximately .43, .87 and 1.7 times the  
 25 maximum human daily dose, respectively, based

<p style="text-align: right;">Page 402</p> <p>1 on body surface area comparison. A</p> <p>2 dose-related reduction in body weights at</p> <p>3 fourth and fifth litter offspring of the</p> <p>4 treated mating pair occurred during lactation</p> <p>5 and post-weaning at all doses. Animals in</p> <p>6 the high-dose group had a reduced number of</p> <p>7 litters per mating pair, male offspring with</p> <p>8 an increased percentage of abnormal sperm and</p> <p>9 reduced birth weights in the next generation</p> <p>10 of pups."</p> <p>11 Doctor, do you know whether or</p> <p>12 not that is the classic exhibition or example</p> <p>13 of a developmental toxicity?</p> <p>14 MS. JOHNSTON: Object to the</p> <p>15 form.</p> <p>16 THE WITNESS: I really don't</p> <p>17 know because I don't do animal work,</p> <p>18 and I have no expertise in animal</p> <p>19 work. So I would not want to comment</p> <p>20 on that.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. And you had -- of course before</p> <p>23 your opinion today, you had not reviewed this</p> <p>24 label?</p> <p>25 A. That's correct. I stated that</p>	<p style="text-align: right;">Page 404</p> <p>1 you know.</p> <p>2 MR. TRACEY: Oh.</p> <p>3 QUESTIONS BY MR. TRACEY:</p> <p>4 Q. Do you prescribe Ultracet,</p> <p>5 ma'am?</p> <p>6 A. Not usually, no.</p> <p>7 Q. Okay. Do you understand it to</p> <p>8 be a mix or a combination of tramadol and</p> <p>9 acetaminophen?</p> <p>10 A. Yeah. It's an opiate and</p> <p>11 acetaminophen, to my knowledge.</p> <p>12 Q. Okay. This label, if you turn</p> <p>13 to the third page, is not 2010 like the</p> <p>14 previous one. It's 2023, if you look down at</p> <p>15 the bottom just to confirm what I said is</p> <p>16 true.</p> <p>17 Do you see that?</p> <p>18 A. Oh, God. I'm having trouble</p> <p>19 following all of these pages here. Can I</p> <p>20 just look at where you are and --</p> <p>21 MS. JOHNSTON: Sean, if you're</p> <p>22 okay, I can help Dr. D'Alton out on</p> <p>23 that. These are right here.</p> <p>24 THE WITNESS: Okay. Got it.</p> <p>25 Thank you.</p>
<p style="text-align: right;">Page 403</p> <p>1 quite a few times today.</p> <p>2 Q. And under that regime, there</p> <p>3 was a Pregnancy Category C based on the oral</p> <p>4 acetaminophen data, right?</p> <p>5 MS. JOHNSTON: Object to the</p> <p>6 form. Asked and answered.</p> <p>7 THE WITNESS: I think it was</p> <p>8 based on the oral and based on no</p> <p>9 studies of intravenous acetaminophen</p> <p>10 in pregnant women. I think it was --</p> <p>11 QUESTIONS BY MR. TRACEY:</p> <p>12 Q. Yes.</p> <p>13 A. -- both.</p> <p>14 (D'Alton Exhibit 915B marked</p> <p>15 for identification.)</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. All right. The next document</p> <p>18 I'll bring up is -- our exhibit is 915B.</p> <p>19 This is the Ultracet label. This is a drug</p> <p>20 made by Janssen Pharmaceuticals.</p> <p>21 Are you familiar with Ultracet?</p> <p>22 MS. JOHNSTON: We're getting</p> <p>23 that label right now, Sean. I</p> <p>24 understand you're not tying that</p> <p>25 question to the label. Just letting</p>	<p style="text-align: right;">Page 405</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. Just lower right-hand corner, I</p> <p>3 just wanted to know that this is a label from</p> <p>4 February of 2023, this year?</p> <p>5 A. Okay.</p> <p>6 Q. The Janssen article, yeah.</p> <p>7 So now what's happened is the</p> <p>8 pregnancy labeling categories are gone and</p> <p>9 the new regime is in place, right, Doctor, in</p> <p>10 2023?</p> <p>11 A. I didn't know it was a regime,</p> <p>12 but a new format is in -- is in place.</p> <p>13 Q. Yeah. Maybe regime is not the</p> <p>14 right word. I don't know what to call it.</p> <p>15 Framework. Regulatory scheme.</p> <p>16 What should we call it?</p> <p>17 A. I think that --</p> <p>18 MS. JOHNSTON: Object to the</p> <p>19 form.</p> <p>20 THE WITNESS: -- sounds better</p> <p>21 than regime.</p> <p>22 QUESTIONS BY MR. TRACEY:</p> <p>23 Q. Yeah, I think so, too.</p> <p>24 Let's call it a new regulatory</p> <p>25 framework.</p>

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1 And then if we flip over to  
 2 pregnancy -- Use in Pregnancy again, 8.1,  
 3 again, on -- no numbers on this.  
 4 MS. JOHNSTON: Sean, while  
 5 she's looking, I think we're coming up  
 6 on time for a break soon.  
 7 MR. TRACEY: Okay. Let's  
 8 just -- this will not be long.  
 9 MS. JOHNSTON: Sure.  
 10 MR. TRACEY: There we go.  
 11 THE WITNESS: One second. I'm  
 12 not -- I'm not here yet. I apologize.  
 13 MS. JOHNSTON: It starts right  
 14 there. Yeah.  
 15 THE WITNESS: Okay. I'm there  
 16 now. Okay.  
 17 QUESTIONS BY MR. TRACEY:  
 18 Q. Okay. Now, have you read  
 19 labels, you know, since the categories have  
 20 changed?  
 21 A. I'm sure that I have read  
 22 labels since the categories have changed,  
 23 yes. Certainly if I'm dealing with a new  
 24 drug, I would look at the label.  
 25 Q. And you know that under the new

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1 framework, they -- the FDA requires drug  
 2 companies to do a risk summary and with combo  
 3 products, each product risk summary needs to  
 4 be done separately as well as together.  
 5 Do you understand that?  
 6 MS. JOHNSTON: Object to the  
 7 form.  
 8 THE WITNESS: Well, no. I --  
 9 as I shared with you, I'm not a  
 10 labeling expert or what is required by  
 11 the FDA to pharmaceutical companies.  
 12 So that is not my area of  
 13 expertise as is fairly obvious today.  
 14 QUESTIONS BY MR. TRACEY:  
 15 Q. Okay. Well, let's just scroll  
 16 down. You do, though, use labels in your  
 17 clinical practice, correct?  
 18 A. Certainly if I'm dealing with a  
 19 new drug, I would look at labels. And if I'm  
 20 familiar with a drug and have used it many  
 21 times and from my review there's no new  
 22 information, I would probably not consult  
 23 with the label.  
 24 Q. All right. Well, let's see  
 25 what they say under the new -- the new

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1 framework.  
 2 You see there's no -- there's  
 3 no longer a pregnancy category, which we  
 4 would expect, right?  
 5 A. Where are we looking now?  
 6 Q. Just at the risk summary --  
 7 A. Okay. The risk summary. Okay.  
 8 Q. Yeah.  
 9 A. So --  
 10 Q. And then the third --  
 11 A. So do you want me to read the  
 12 risk summary or --  
 13 Q. No, ma'am.  
 14 A. Okay.  
 15 Q. The third paragraph down, we're  
 16 beginning to see the exact same language in  
 17 this label that we just read about  
 18 acetaminophen in the Cadence label.  
 19 And so let's just do that. It  
 20 says, "Reproductive and developmental studies  
 21 in rats and mice from the published  
 22 literature identified adverse events at  
 23 clinically relevant doses with acetaminophen.  
 24 "Treatment of pregnant rats  
 25 with doses of acetaminophen, approximately

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1 1.3 times the maximum human daily dose,  
 2 showed evidence of fetotoxicity and increases  
 3 in bone variations in the fetus."  
 4 Do you remember reading that?  
 5 MS. JOHNSTON: Object to --  
 6 object to the form.  
 7 THE WITNESS: I can't remember  
 8 the exact numbers around it, but I  
 9 remember reading something similar to  
 10 this in the previous -- in some  
 11 versions of the previous documents you  
 12 showed me.  
 13 QUESTIONS BY MR. TRACEY:  
 14 Q. Okay. And then they go on to  
 15 say, "In another study, necrosis was observed  
 16 in the liver and kidney of both pregnant rats  
 17 and fetuses at doses approximately 1.9 times  
 18 the maximum human daily dose.  
 19 "In mice treated with  
 20 acetaminophen at doses within the clinical  
 21 dosing range, cumulative adverse effects on  
 22 reproduction were seen in a continuous  
 23 breeding study. A reduction in the number of  
 24 litters of the parental mating pair -- of the  
 25 parental mating pair was observed as well as

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1 retarded growth and abnormal sperm in their  
 2 offspring and reduced birth weight in the  
 3 next generation. See data.  
 4 "Based on animal data, advise  
 5 pregnant women of the potential risk to a  
 6 fetus."  
 7 Do you see that, ma'am?  
 8 MS. JOHNSTON: Object to the  
 9 form.  
 10 THE WITNESS: I do.  
 11 QUESTIONS BY MR. TRACEY:  
 12 Q. You have never seen that  
 13 before, have you, ma'am?  
 14 A. No, I have not.  
 15 Q. And you have never once advised  
 16 a pregnant woman of the potential risk to her  
 17 fetus based on this data?  
 18 A. Well --  
 19 MS. JOHNSTON: Object to the  
 20 form.  
 21 THE WITNESS: -- seeing as I've  
 22 never seen it before, I would not make  
 23 recommendations to patients on  
 24 something I've never seen.  
 25

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1 QUESTIONS BY MR. TRACEY:  
 2 Q. Fair enough. Good point.  
 3 Now, are you aware of anywhere  
 4 on a Tylenol label ever in an  
 5 over-the-counter medicine this language or  
 6 similar language communicated to doctors or  
 7 to patients?  
 8 MS. JOHNSTON: Object to the  
 9 form.  
 10 THE WITNESS: I would have to  
 11 look at the labels. I'm not aware --  
 12 on the oral acetaminophen, it is  
 13 not -- it is not there. On IV  
 14 admin -- acetaminophen, I'd have to  
 15 look at that.  
 16 QUESTIONS BY MR. TRACEY:  
 17 [REDACTED]  
 18 [REDACTED]  
 19 MS. JOHNSTON: Hey, Sean, are  
 20 we at place before we get that  
 21 document --  
 22 MR. TRACEY: Yeah.  
 23 MS. JOHNSTON: -- can we --  
 24 MR. TRACEY: Yeah, sorry.  
 25 MS. JOHNSTON: No problem.

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1 MR. TRACEY: Ten minutes again?  
 2 MS. JOHNSTON: Yes, please.  
 3 VIDEOGRAPHER: The time is  
 4 5:23, and we are off the record.  
 5 (Off the record at 5:23 p.m.)  
 6 VIDEOGRAPHER: The time right  
 7 now is 5:40 p.m. We are back on the  
 8 record.  
 9 [REDACTED]

[REDACTED]

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25 THE WITNESS: I'm just

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1 responding to the statement here.  
 2 What I said in my previous statement  
 3 was you said nothing had changed. And  
 4 I said, well, a lot has changed  
 5 because these categories are not being  
 6 used anymore.  
 7 And as I understand it,  
 8 IV acetaminophen was Category C  
 9 because of the combination of animal  
 10 data and the effect on the animal  
 11 studies data.  
 12 QUESTIONS BY MR. TRACEY:  
 13 Q. Yes, ma'am.  
 14 And that's what I meant hasn't  
 15 changed. There are no adequate and  
 16 well-controlled studies even to this day in  
 17 acetaminophen. You and I have already talked  
 18 about this, right?  
 19 A. Yeah. I think that's my point  
 20 today, that there is no adequate trials for  
 21 which I can assess risk of ADHD and ASD  
 22 related to prenatal use of acetaminophen.  
 23 Q. And the reason there are no  
 24 adequate and well-controlled studies,  
 25 Dr. Pinto-Martin told us two days ago, is

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1 because it would be unethical to do it,  
 2 right?  
 3 MS. JOHNSTON: Object to the  
 4 form and say that Dr. Pinto-Martin's  
 5 testimony speaks for itself.  
 6 THE WITNESS: That's --  
 7 MR. TRACEY: Indeed it does.  
 8 THE WITNESS: That's what she  
 9 said, and I think it depends on the  
 10 study whether it would be unethical or  
 11 not, and I would need to know more  
 12 about the design.  
 13 And certainly I would agree  
 14 with doing more studies and doing more  
 15 research studies in pregnant women as  
 16 has been called for by many  
 17 investigators, and I would recommend  
 18 that.  
 19 So we could clarify any  
 20 questions related to the use of -- the  
 21 current knowledge that we have around  
 22 acetaminophen -- prenatal  
 23 acetaminophen use and its  
 24 associated -- and its reported  
 25 associations.

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1 QUESTIONS BY MR. TRACEY:  
 2 Q. Doctor, do you think there's a  
 3 world in which -- that exists where we're  
 4 going to randomize women to -- pregnant women  
 5 to acetaminophen to see what happens to their  
 6 babies? Do you really think that's going to  
 7 happen?  
 8 MS. JOHNSTON: Object to the  
 9 form.  
 10 THE WITNESS: Well, we would  
 11 need to have an alternative because  
 12 a -- as I've said to you this morning  
 13 is that treatment of pain is a human  
 14 right.  
 15 So in order to randomize  
 16 patients, one would need to have a  
 17 safe alternative to test it against.  
 18 Because it would not be ethical to  
 19 test it against a placebo for  
 20 treatment of pain and fever.  
 21 So with respect to doing a  
 22 placebo-controlled trial, I would  
 23 agree with that because it would be --  
 24 it would be unethical to hold -- to  
 25 withhold a medication from a mother

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1 that was effective for treating pain  
 2 and fever.  
 3 Now, I think there's --  
 4 QUESTIONS BY MR. TRACEY:  
 5 Q. What about --  
 6 A. -- there's observational trials  
 7 that could be done.  
 8 MS. JOHNSTON: Did you complete  
 9 your answer, Doctor?  
 10 QUESTIONS BY MR. TRACEY:  
 11 Q. What about the evidence of  
 12 exposing the fetus that Dr. Pinto-Martin  
 13 seemed to be concerned about? Are you  
 14 concerned about that?  
 15 MS. JOHNSTON: Object again.  
 16 THE WITNESS: I'm always  
 17 concerned about both. I'm always  
 18 concerned about the mother and the  
 19 fetus, and in designing a trial, I  
 20 would always be -- express concern for  
 21 any -- for any fetal effects or  
 22 maternal effects.  
 23 So I'm a worrier, so I would  
 24 worry about the design of a clinical  
 25 trial, and you've asked me about what

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1 I thought about the ethics of doing  
2 this, and my main concern is the  
3 ethics of doing this is there's no  
4 safe alternative to the use of  
5 acetaminophen in pregnancy for  
6 treatment of pain and fever.  
7 QUESTIONS BY MR. TRACEY:  
8 Q. Okay. I tell you what I want  
9 to do now. Ray, will you go to  
10 tylenolprofessional.com It's a website.  
11 There's no other way to do  
12 this, Doctor.  
13 Have you ever been to this  
14 website, tylenolprofessional.com  
15 A. I don't know at this point. I  
16 can't remember that I have, but I don't know.  
17 MR. TRACEY: Can you make that  
18 bigger, Ray, so we can -- we can pull  
19 it up and -- is this the actual  
20 website, or is this the search for  
21 pregnancy?  
22 RAY MOORE: This is the website  
23 the way I received it. I mean, I can  
24 go wherever you want, but this is out  
25 of link --

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1 MS. JOHNSTON: Yeah, and --  
2 and, Sean --  
3 MR. TRACEY: I guess what I'm  
4 asking --  
5 MS. JOHNSTON: -- I just want  
6 to clarify, is this a static  
7 screenshot? Are we looking at a  
8 website? I'm confused about what this  
9 is.  
10 MR. TRACEY: Yeah, so that's my  
11 question.  
12 Ray, is this -- is this a live  
13 website, or is this just a screenshot?  
14 RAY MOORE: This is a live  
15 website. This is the way that the  
16 link opened up.  
17 MR. TRACEY: Oh, good.  
18 QUESTIONS BY MR. TRACEY:  
19 Q. Okay. So let's do it so  
20 Dr. D'Alton sees.  
21 You see this, Doctor, this is a  
22 Tylenol website for health care  
23 professionals.  
24 Do you see that?  
25 A. I do.

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1 Q. Now, you said you don't know or  
2 can't remember if you've been here to see if  
3 a doctor has a question about Tylenol in  
4 pregnancy what exactly Johnson & Johnson  
5 reveals.  
6 Is that right?  
7 MS. JOHNSTON: Object to the  
8 form.  
9 THE WITNESS: I said I don't  
10 recall if I have been here, and so I  
11 can't tell you that with any deal of  
12 accuracy this afternoon.  
13 QUESTIONS BY MR. TRACEY:  
14 Q. Okay. Will you type in  
15 "pregnancy" in the search bar and hit send?  
16 There you go, you got it. Just hit send  
17 or -- there you go.  
18 Do you see, Dr. D'Alton, that  
19 when we search on the Tylenol health care  
20 professional website for pregnancy in  
21 Tylenol, we get zero results?  
22 Do you see that?  
23 MS. JOHNSTON: And I'll just  
24 object that this is counsel's  
25 direction on how to use this website,

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1 and it speaks for itself.  
2 But, Dr. D'Alton, of course you  
3 can answer the question.  
4 THE WITNESS: I see what's in  
5 front of me, Mr. Tracey, yes.  
6 QUESTIONS BY MR. TRACEY:  
7 Q. So if I'm a doctor and I have a  
8 question about the safety of Tylenol in  
9 pregnancy and I go to the manufacturer of it,  
10 their website that says it's for me, a  
11 doctor, I get no information.  
12 MS. JOHNSTON: Object to the  
13 form. Same objections.  
14 QUESTIONS BY MR. TRACEY:  
15 Q. Right?  
16 A. Your research revealed no  
17 results is what it would say, from this  
18 document in front of me.  
19 Q. And it actually said, "Did you  
20 mean preference?"  
21 Do you see that?  
22 MS. JOHNSTON: Same objections.  
23 THE WITNESS: I do see that,  
24 yes.  
25

<p style="text-align: right;">Page 426</p> <p>1 QUESTIONS BY MR. TRACEY:</p> <p>2 Q. How can it be -- Doctor, can</p> <p>3 you think of a reason why, based on what I</p> <p>4 have looked at in the past few hours, how it</p> <p>5 can be that if a doctor wanted information</p> <p>6 from the manufacturer, the latest and</p> <p>7 greatest, like you put in the preface in your</p> <p>8 book, from the manufacturer that there's</p> <p>9 nothing there?</p> <p>10 MS. JOHNSTON: Object to the</p> <p>11 form.</p> <p>12 THE WITNESS: You know, as I've</p> <p>13 stated, I'm not knowledgeable about</p> <p>14 what is -- should be placed into</p> <p>15 documents by pharmaceutical companies,</p> <p>16 but there's plenty of other sources</p> <p>17 where a physician could go to find out</p> <p>18 information with respect to Tylenol</p> <p>19 and its safety in pregnancy.</p> <p>20 QUESTIONS BY MR. TRACEY:</p> <p>21 Q. That's really, really true.</p> <p>22 Have you ever used the book</p> <p>23 Briggs on Pregnancy and Lactation, a Guide</p> <p>24 for Doctors to Medications?</p> <p>25 A. Yes, I've used it as a</p>	<p style="text-align: right;">Page 428</p> <p>1 THE WITNESS: Yes, I have it.</p> <p>2 QUESTIONS BY MR. TRACEY:</p> <p>3 Q. So Briggs is actually -- this</p> <p>4 book is in its twelfth edition, Drugs in</p> <p>5 Pregnancy and Lactation, right, Doctor?</p> <p>6 A. Yes.</p> <p>7 Q. You've used this in your</p> <p>8 practice in the past?</p> <p>9 A. Yes, I have.</p> <p>10 Q. It's a well-known reference</p> <p>11 guide for doctors related to drugs in</p> <p>12 pregnancy, correct?</p> <p>13 A. I think it's a well-known</p> <p>14 reference guide, yes.</p> <p>15 Q. And if we flip over to the</p> <p>16 acetaminophen section, which, again, I don't</p> <p>17 see a page number on mine, but -- so I don't</p> <p>18 know how to tell you, Ray, how to get there,</p> <p>19 but it's just on this -- there you go.</p> <p>20 And they've got</p> <p>21 recommendations, don't they?</p> <p>22 A. Yes, they do.</p> <p>23 Q. They say, "Short-term use</p> <p>24 suggests low risk."</p> <p>25 Right?</p>
<p style="text-align: right;">Page 427</p> <p>1 reference text.</p> <p>2 Q. When is the last time you</p> <p>3 looked at Briggs and Tylenol?</p> <p>4 A. I looked at it when I was</p> <p>5 preparing my report because I noticed that</p> <p>6 Dr. Baccarelli wrote that it was an</p> <p>7 authoritative text. So because of that, I</p> <p>8 look at Briggs and looked at what their</p> <p>9 intent was in giving patients and giving</p> <p>10 physicians information.</p> <p>11 (D'Alton Exhibit 908 marked for</p> <p>12 identification.)</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. And this is Exhibit 908, Ray.</p> <p>15 Let's pull up Briggs.</p> <p>16 It's called a Reference Guide</p> <p>17 to Fetal and Neonatal Risk, right, Doctor?</p> <p>18 A. Yes, I'm just waiting to get it</p> <p>19 in front of me. I see the picture, but they</p> <p>20 have not brought the exhibit to me. And I</p> <p>21 think I should have it momentarily.</p> <p>22 Q. Let me know when you get it,</p> <p>23 please.</p> <p>24 MS. JOHNSTON: We've got it,</p> <p>25 Sean.</p>	<p style="text-align: right;">Page 429</p> <p>1 A. Yes.</p> <p>2 Q. And then long-term use suggests</p> <p>3 risks, right?</p> <p>4 MS. JOHNSTON: Object to the</p> <p>5 form.</p> <p>6 THE WITNESS: That's what it</p> <p>7 states here, yes.</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. Now, as far as you know, do</p> <p>10 these guys work for Johnson &amp; Johnson?</p> <p>11 MS. JOHNSTON: Object to the</p> <p>12 form.</p> <p>13 THE WITNESS: I don't know of</p> <p>14 any relationship that they have with</p> <p>15 Johnson &amp; Johnson.</p> <p>16 QUESTIONS BY MR. TRACEY:</p> <p>17 Q. Okay. Under Pregnancy Summary,</p> <p>18 let's see what they say. They say,</p> <p>19 "Acetaminophen, paracetamol or APAP, is</p> <p>20 commonly used in all stages of pregnancy.</p> <p>21 Although originally thought not to cause</p> <p>22 embryo-fetal harm, this assessment must</p> <p>23 change because of recent data."</p> <p>24 Did I read that correctly?</p> <p>25 A. Yes.</p>

<p>Page 430</p> <p>1 Q. Do you know whether your 2 medical school uses Briggs to train medical 3 students and residents? 4 MS. JOHNSTON: Object to the 5 form. 6 THE WITNESS: I mean, it may be 7 used as a reference guide, like a 8 number of textbooks are, to -- in 9 medical school, and -- but I would 10 disagree that it is authoritative. 11 And I don't agree with this 12 comment that's written here, that this 13 assessment must change because of 14 recent data. 15 QUESTIONS BY MR. TRACEY: 16 Q. No, no, I understand you don't 17 agree. But my question was, do you know 18 whether or not this reference is used in the 19 medical school that employs you? 20 MS. JOHNSTON: Same objections. 21 THE WITNESS: Well, I would 22 usually be the one who is deciding on 23 what's used in the medical school for 24 training of residents around 25 obstetrical risk. So it is a -- it</p>	<p>Page 432</p> <p>1 was authoritative. 2 Q. Okay. They go on to say, 3 "Although the risk is very low, use of the 4 drug for several weeks or longer has been 5 associated with cryptorchidism, decreased IQ, 6 ADHD and other problems in neurodevelopment." 7 Did I read that correctly? 8 A. You read that correctly. 9 Q. And, of course, as you've said, 10 you disagree with the Briggs reference guide? 11 MS. JOHNSTON: Object to the 12 form. 13 THE WITNESS: I disagree with 14 it for several reasons. 15 QUESTIONS BY MR. TRACEY: 16 Q. Do you know how many -- oh. 17 Did you -- did you ever know Gerald Briggs? 18 A. No, I didn't know Gerald 19 Briggs. I know Roger Freeman very well who 20 was the maternal-fetal medicine specialist 21 that was a coauthor on previous editions, and 22 I'm not familiar with Dr. Towers, who's the 23 maternal-fetal medicine who is on this 24 document. 25 But certainly if he contributed</p>
<p>Page 431</p> <p>1 certainly is a reference text that may 2 be useful in providing information to 3 patients in their reference -- or 4 sorry, excuse me, to physicians in 5 their reference list. 6 QUESTIONS BY MR. TRACEY: 7 Q. Okay. Do you have a copy of 8 this in your office? I don't even know if 9 you have books anymore. 10 But do you still use books? 11 A. I mean, it's less and less. I 12 was more of a Neanderthal years ago when I 13 used books for everything, but now because of 14 most books are out of date by the time 15 they've been published, I usually go to 16 online sources. 17 Q. Do you have a copy of the 18 hard -- do you have a hardcopy of an edition 19 of this book, or would you just reference it 20 online or both? 21 A. I would probably do both 22 because I read better -- when I want to take 23 in a document, I read better when it is 24 printed, but I did order a copy of this book 25 when I read Dr. Baccarelli's report that it</p>	<p>Page 433</p> <p>1 to this portion of the document, his opinions 2 are at odds with pretty much all of our 3 medical societies around the world that 4 represent obstetrician, gynecologist and 5 teratologists. 6 Q. That seems really odd to me. 7 MS. JOHNSTON: Just wait for a 8 question. 9 QUESTIONS BY MR. TRACEY: 10 Q. Why would these doctors, these 11 scientists, looking at the same data, come to 12 such starkly different conclusions than your 13 societies? 14 MS. JOHNSTON: Object to the 15 form. 16 THE WITNESS: Well, first of 17 all, they don't really say why they 18 come to their conclusions because they 19 don't analyze the information in the 20 references that they provide in 21 this -- in this document related to 22 those references that are there -- 23 that are in the neurodevelopmental 24 section. 25 And they state what the authors</p>

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1 have published, but they don't state  
 2 any analysis of the -- of the authors'  
 3 publications. So it's really left to  
 4 the individual practitioner to go to  
 5 those references and decide for  
 6 themselves the risks and -- or sorry,  
 7 the strengths and weaknesses of those  
 8 studies like we've discussed today.  
 9 So in my opinion, the analysis  
 10 of this -- of the document of this --  
 11 document in Briggs and Towers, and I  
 12 don't remember the name of the other  
 13 author, Forinash, another  
 14 pharmacologist, fall short of their  
 15 intent in the book.  
 16 QUESTIONS BY MR. TRACEY:  
 17 Q. Well, the ACOG reference had  
 18 zero references, the ACOG statement.  
 19 Remember that?  
 20 MS. JOHNSTON: Object to the  
 21 form.  
 22 THE WITNESS: Well, that's  
 23 certainly -- it did have zero  
 24 references but recall at that time  
 25 when the -- when ACOG wrote its

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1 statement, it was in direct response  
 2 to Dr. Bauer and her colleagues asking  
 3 that professional societies respond by  
 4 updating their documents.  
 5 And in short order, ACOG  
 6 responded. Then ENTIS responded to  
 7 the -- the teratology information  
 8 services from the US -- or sorry, UK  
 9 and Europe, and also the Canadian  
 10 college responded in short order.  
 11 And then following that, there  
 12 was a number of other societies, 16  
 13 organizations from around the world  
 14 who signed a document that was in a  
 15 direct response to Dr. Bauer in -- in  
 16 the same journal that she reported and  
 17 gave several reasons why they were not  
 18 agreeing with the document.  
 19 And ACOG is one of the  
 20 signatories on that, as are 16  
 21 international OB/GYN societies.  
 22 QUESTIONS BY MR. TRACEY:  
 23 Q. Do you know what Epocrates is?  
 24 A. I do know what Epocrates is.  
 25 It's a -- it's an online book that is used

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1 for various information related to medical  
 2 care.  
 3 Q. Have you looked up what they  
 4 have to say about acetaminophen?  
 5 A. I believe that I did, and that  
 6 it was safe for use in pregnancy.  
 7 Q. It was what?  
 8 A. That it was safe for use in  
 9 pregnancy, as best I can recollect it.  
 10 (D'Alton Exhibit 906 marked for  
 11 identification.)  
 12 QUESTIONS BY MR. TRACEY:  
 13 Q. Well, let's look at it. It's  
 14 Exhibit 906.  
 15 MS. JOHNSTON: Just getting a  
 16 copy.  
 17 QUESTIONS BY MR. TRACEY:  
 18 Q. And this is -- this is off the  
 19 Epocrates website.  
 20 This is for health care  
 21 practitioners, right?  
 22 A. Yes. Let me just look at it.  
 23 Q. And the pregnancy section is  
 24 18, page 18. Clinical summary.  
 25 A. I can't find it here. Sorry.

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1 Q. Maybe you should look at the  
 2 screen, Doctor.  
 3 MS. JOHNSTON: Yeah, sorry.  
 4 This is page 10. We're going page 18.  
 5 THE WITNESS: Okay. Got it.  
 6 QUESTIONS BY MR. TRACEY:  
 7 Q. Okay. "May use during  
 8 pregnancy; drug of choice for analgesic and  
 9 antipyretic use during pregnancy; no known  
 10 risk of fetal harm with short-term use based  
 11 on human data with the oral form; possible  
 12 risk of cryptorchidism and adverse  
 13 neurodevelopmental disorders with long-term  
 14 use based on limited human data with oral  
 15 form."  
 16 Did you know that Epocrates had  
 17 this?  
 18 A. Well, it says -- first of all,  
 19 that it's the drug of choice --  
 20 Q. Yes.  
 21 A. -- for analgesic and  
 22 antipyretic use during pregnancy.  
 23 And I certainly knew that it  
 24 said no known risk of fetal harm.  
 25 And then it says, "A possible

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1 risk."

2 Q. Long-term use.

3 A. I'm sorry, I didn't hear what

4 you said. I apologize.

5 Q. Well, I was going to make --

6 A. You were interrupting me, and I

7 just was trying to -- I'm trying to read it,

8 and I've lost my train of thought,

9 unfortunately.

10 Q. Okay. Well, let's read it

11 together so we can read it accurately.

12 It says, "No known risk of

13 fetal harm with short-term use based on human

14 data with the oral form; possible risk of

15 cryptorchidism and adverse neurodevelopmental

16 outcomes with long-term use based on limited

17 human data with oral form."

18 That's what it says, right?

19 A. That's what it says. It says

20 there's a possible risk based on limited

21 human data.

22 Q. And when -- yes, ma'am.

23 And when you were citing all of

24 the societies in your report, you didn't cite

25 either Briggs or Epocrates in your report,

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1 did you?

2 A. Well, no, I didn't, because

3 none of them are societies; they're

4 textbooks.

5 And I did cite what Briggs'

6 intent was in my report, and I mentioned that

7 their intent was to provide information to

8 practicing clinicians so that they could make

9 decisions about the pros and cons of

10 prescribing in pregnancy.

11 And in my opinion, they fell

12 short of the mark here based on what I've

13 shared with you today.

14 Q. Ma'am, are you aware of another

15 publication called StatPearls that is put out

16 by the National Institutes of Health?

17 A. No, I'm -- I might have seen

18 it, but I can't recall it at this precise

19 moment.

20 (D'Alton Exhibit 909 marked for

21 identification.)

22 QUESTIONS BY MR. TRACEY:

23 Q. This is Exhibit 909, Ray.

24 This is a publication that is

25 put out by the federal government. And if

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1 you'll look down at the bottom, you'll see

2 the website --

3 A. Sorry, can I just get it?

4 MS. JOHNSTON: Yeah. And,

5 Sean, it's -- the scrolling, I think,

6 is kind of getting to be a bit much,

7 so we just need to get the copy.

8 THE WITNESS: It's giving me

9 the need for Tylenol.

10 MR. TRACEY: Don't overdose.

11 THE WITNESS: Don't worry.

12 QUESTIONS BY MR. TRACEY:

13 Q. Read that black box.

14 All right. So you see there,

15 what we have highlighted? It's from the NIH?

16 A. Sorry, where -- which page are

17 we on now?

18 MS. JOHNSTON: He's talking

19 about --

20 QUESTIONS BY MR. TRACEY:

21 Q. Any page. It's at the bottom.

22 A. Okay. Okay.

23 Q. It's the URL.

24 A. Yeah.

25 Q. You recognize this is the NIH

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1 site, <http://nih.gov/books?>

2 MS. JOHNSTON: I object to the

3 form and -- okay.

4 THE WITNESS: I think it's --

5 QUESTIONS BY MR. TRACEY:

6 Q. Yes or no?

7 A. I'm sorry, it doesn't say that

8 it's an NIH document. It says it's a service

9 of the National Library of Medicine. It

10 doesn't say it's from the NIH.

11 Q. Yes, ma'am.

12 It says it's a service of the

13 National Library of Medicine, which is run by

14 the federal government of the United States,

15 right?

16 MS. JOHNSTON: Object to the

17 form.

18 THE WITNESS: Yes, but it

19 doesn't say that they published this

20 document. This is Treasure Island,

21 Florida, StatPearls Publishing. That

22 does not indicate to me this is the

23 NIH.

24 QUESTIONS BY MR. TRACEY:

25 Q. We'll argue about this later,

<p style="text-align: right;">Page 442</p> <p>1 ma'am, but flip over to the fourth page. At</p> <p>2 the top again, it says, "Acetaminophen -</p> <p>3 StatPearls - NCBI Bookshelf."</p> <p>4 And there in the middle it</p> <p>5 says, "Pregnant women should exercise caution</p> <p>6 when using acetaminophen early in pregnancy</p> <p>7 because of increasing evidence that in utero</p> <p>8 acetaminophen exposure to the fetus might</p> <p>9 increase the risk of neurological,</p> <p>10 reproductive and urogenital disorders," and</p> <p>11 they cite the Alemany study, among others.</p> <p>12 Right?</p> <p>13 A. Well, number 11, they cite</p> <p>14 Bauer. That's the reference they cite for</p> <p>15 that.</p> <p>16 And I'm pretty confident this</p> <p>17 is not an NIH document.</p> <p>18 Q. Where -- number 11 says</p> <p>19 Alemany -- Alemany.</p> <p>20 A. No, I think number 11 says</p> <p>21 Bauer in my -- in the one I have.</p> <p>22 Q. Are you looking at the screen?</p> <p>23 MS. JOHNSTON: No. Sean --</p> <p>24 THE WITNESS: I'm looking at</p> <p>25 the screen, and it says 11. And if</p>	<p style="text-align: right;">Page 444</p> <p>1 stated in her -- in her report, in the</p> <p>2 Bauer 2021 document that I've already</p> <p>3 said has gotten very substantial</p> <p>4 response from the professional</p> <p>5 societies, like she asked for, like</p> <p>6 she and her authors asked for, in</p> <p>7 their publication.</p> <p>8 QUESTIONS BY MR. TRACEY:</p> <p>9 Q. Ma'am, you're not answering my</p> <p>10 question.</p> <p>11 MS. JOHNSTON: She's absolutely</p> <p>12 answering question now.</p> <p>13 QUESTIONS BY MR. TRACEY:</p> <p>14 Q. Now you're just giving a</p> <p>15 speech.</p> <p>16 MS. JOHNSTON: She's absolutely</p> <p>17 answering your question.</p> <p>18 THE WITNESS: I am answering</p> <p>19 your question, Mr. Tracey. This one I</p> <p>20 am answering very clearly.</p> <p>21 QUESTIONS BY MR. TRACEY:</p> <p>22 Q. What question are you</p> <p>23 answering?</p> <p>24 A. I'm answering your question</p> <p>25 about reference 11 here --</p>
<p style="text-align: right;">Page 443</p> <p>1 you go to the back where the</p> <p>2 reference 11 is, that is Bauer.</p> <p>3 QUESTIONS BY MR. TRACEY:</p> <p>4 Q. Oh, okay. Let's start over.</p> <p>5 What StatPearls said is that,</p> <p>6 "Pregnant should exercise caution when using</p> <p>7 acetaminophen early in pregnancy because of</p> <p>8 increasing evidence that in utero</p> <p>9 acetaminophen exposure to the fetus might</p> <p>10 increase the risk of neurological,</p> <p>11 reproductive and urogenital disorders.</p> <p>12 "Alemany, et al., studied</p> <p>13 prenatal and postnatal acetaminophen exposure</p> <p>14 in relation to autism spectrum disorder and</p> <p>15 attention-deficit disorder."</p> <p>16 Right?</p> <p>17 That's the Alemany reference,</p> <p>18 and then they go on and explain it, right?</p> <p>19 MS. JOHNSTON: Object to the</p> <p>20 form. I'm not sure what the question</p> <p>21 is.</p> <p>22 THE WITNESS: I mean,</p> <p>23 number 11 -- I'm sorry, you asked me</p> <p>24 what the reference was. Number 11 is</p> <p>25 clearly Bauer, and that's what Bauer</p>	<p style="text-align: right;">Page 445</p> <p>1 Q. I didn't -- ma'am, that was</p> <p>2 three questions ago. I asked you about</p> <p>3 Alemany.</p> <p>4 Do you recognize the yellow as</p> <p>5 being from the Alemany meta-analysis?</p> <p>6 A. Yes. I recognize that from the</p> <p>7 meta-analysis and what I've shared with you</p> <p>8 earlier about meta-analysis --</p> <p>9 Q. That was my only question.</p> <p>10 MS. JOHNSTON: That's fine.</p> <p>11 THE WITNESS: Okay. Great.</p> <p>12 QUESTIONS BY MR. TRACEY:</p> <p>13 Q. That's my only question.</p> <p>14 A. Oh, that's perfect.</p> <p>15 Q. Okay. Now, have you ever been</p> <p>16 on the StatPearls website before?</p> <p>17 A. No. And it says StatPearls is</p> <p>18 Treasure Island, Florida, StatPearls</p> <p>19 Publishing, and this is a service of the</p> <p>20 National Library of Medicine, who will find</p> <p>21 these articles.</p> <p>22 So I am certainly not confident</p> <p>23 from a review of this that this is a</p> <p>24 publication of the NIH.</p> <p>25 Q. Well, the URL below is from the</p>

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1 NIH, right?

2 MS. JOHNSTON: Object to the

3 form. Asked and answered.

4 THE WITNESS: Well, the URL is

5 the library of the NIH. That doesn't

6 mean that the document was published

7 by the NIH. It's present in their

8 library.

9 QUESTIONS BY MR. TRACEY:

10 Q. Is this one causing you some

11 heartburn?

12 MS. JOHNSTON: Objection.

13 THE WITNESS: Oh, no, no. It's

14 not causing me any heartburn.

15 I'm just trying to clarify that

16 nowhere states this -- nowhere does it

17 state here, except for StatPearls,

18 Treasure Island, Florida, StatPearls

19 Publishing, that this is a publication

20 of the NIH.

21 QUESTIONS BY MR. TRACEY:

22 Q. What's the date on this, ma'am,

23 up in the left-hand corner?

24 A. I have 9/5/23, 1:52 p.m.

25 Q. Three days ago, right?

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1 A. I believe that's when it was

2 searched, yes.

3 Q. I'm assuming you disagree with

4 what is on the screen; is that correct?

5 A. Well, I do, because what's on

6 the screen was available prior to this.

7 We've -- we know that Bauer is 2021, and we

8 know that Alemany is 2022, as best I can

9 recollect. You know, sorry, it's also 2021,

10 so this information is not new.

11 Q. No, ma'am. It's just another

12 source citing the same information for

13 reasons that you disagree with.

14 MS. JOHNSTON: Just let him ask

15 you a question. He's testifying at

16 this point.

17 QUESTIONS BY MR. TRACEY:

18 Q. Let me ask you this. So we've

19 gone through Epocrates, we've gone through

20 Briggs, and now we've gone through the

21 National Library of Medicine site here.

22 And it is true that you

23 disagree with all three of those sources and

24 what they say about acetaminophen?

25 MS. JOHNSTON: Same objections,

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1 and I won't make Dr. D'Alton repeat

2 what she's already said particularly

3 about this source, but --

4 THE WITNESS: I disagree --

5 MS. JOHNSTON: One second. Let

6 me just get this out.

7 THE WITNESS: Sorry.

8 MS. JOHNSTON: Fine. Sean,

9 yes, you're creative comments --

10 MR. TRACEY: You're cutting

11 out. Yeah, I can't hear anything.

12 MS. JOHNSTON: No, it's fine.

13 Ask what you need to ask.

14 QUESTIONS BY MR. TRACEY:

15 Q. Ma'am, it's true that you

16 disagreed with Briggs, you disagreed with

17 Epocrates, and you disagreed with this

18 website, whatever the source is?

19 A. No, that's actually not true.

20 I agreed with many of the -- of the

21 statements that you showed me related -- in

22 Epocrates. I am -- agreed with you that

23 that's what they stated in Briggs, but I felt

24 I shared with you the reasons why I fell

25 short -- I felt that Briggs fell short of its

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1 stated intent to provide information to

2 clinicians because it left the clinician to

3 have to go and look at those articles on

4 their own to understand the strengths and

5 weaknesses.

6 And importantly and with

7 relation to Briggs, Briggs was published in

8 2022, and it did not cite many of the

9 articles that have been published that we've

10 discussed here today that were from SMFM, it

11 did not, which surprised me that a

12 maternal-fetal medicine physician --

13 Q. That's not a study, ma'am.

14 That's not a study.

15 MS. JOHNSTON: You can finish

16 your response.

17 QUESTIONS BY MR. TRACEY:

18 Q. That's an opinion piece.

19 MS. JOHNSTON: You can finish

20 your response, Dr. D'Alton.

21 It's been a really long day,

22 Sean. This has to stop.

23 THE WITNESS: Well, an opinion

24 piece was written by Bauer, and

25 opinion pieces were written in

<p style="text-align: right;">Page 450</p> <p>1 response to Bauer. So these are 2 the -- Briggs is a textbook, and this 3 is StatPearls. So they're all 4 different things. 5 QUESTIONS BY MR. TRACEY: 6 Q. Yes, ma'am. 7 They're all different things, 8 all saying the same or similar things about 9 Tylenol? 10 MS. JOHNSTON: He's just 11 testifying. Let him ask you a 12 question. 13 MR. TRACEY: No, no. That's a 14 question. 15 MS. JOHNSTON: It really 16 wasn't. 17 MR. TRACEY: Well, I don't know 18 how to convince you that that's a 19 question, but it is. 20 THE WITNESS: Well, I'm going 21 to -- 22 MS. JOHNSTON: He's asking you 23 if there's three different sources. 24 THE WITNESS: There's certainly 25 three different sources here.</p>	<p style="text-align: right;">Page 452</p> <p>1 source of maternal-fetal medicine physicians 2 that are available in the -- in the US, at 3 least, is the Society for Maternal-Fetal 4 Medicine, which has, I think, almost -- I 5 forget how many members, 3,000 members, maybe 6 it's more than that, and many international 7 members. 8 So I felt that would be a very 9 good source to go to to know about the 10 issues -- or the thoughts of maternal-fetal 11 medicine physicians. So I have not -- I am 12 not aware of anyone in the Society with 13 the -- with the exception of Dr. Towers who 14 has said there's a risk. 15 Q. Do you remember my question, 16 Doctor? 17 MS. JOHNSTON: Object to the 18 form. 19 THE WITNESS: You asked me if I 20 had gone to the Internet. I didn't go 21 to the Internet. I went to directly 22 to the Society -- 23 QUESTIONS BY MR. TRACEY: 24 Q. No, no. That's not what I 25 asked you.</p>
<p style="text-align: right;">Page 451</p> <p>1 MS. JOHNSTON: There we go. 2 QUESTIONS BY MR. TRACEY: 3 Q. Ma'am, have you surveyed the 4 literature on the Internet looking for 5 maternal-fetal medicine or OB/GYN experts in 6 the field to disagree with you about Tylenol? 7 MS. JOHNSTON: Object to the 8 form. 9 THE WITNESS: I certainly 10 haven't searched the Internet, but I 11 have been in touch with the Society 12 for Maternal-Fetal Medicine and their 13 publications committee, and also with 14 ACOG to see if they are updating their 15 documents. 16 And I wanted to be up to date 17 with what their intent was. At this 18 point they have -- they do not feel 19 that there is a need to update their 20 documents, so I -- 21 QUESTIONS BY MR. TRACEY: 22 Q. Do you remember my question? 23 A. Yes. You asked me about other 24 maternal-fetal medicine physicians who would 25 be on the Internet, and I think the largest</p>	<p style="text-align: right;">Page 453</p> <p>1 I asked you, Doctor, not 2 whether you went to the Internet. I asked 3 you whether or not you went to the Internet, 4 and you searched to find out if there are 5 other qualified, competent OB/GYNs or 6 maternal-fetal medicine experts that disagree 7 with you. 8 That's my question. It's 9 either yes or no. 10 MS. JOHNSTON: Object to the 11 form. 12 THE WITNESS: No, I have not 13 done that. 14 QUESTIONS BY MR. TRACEY: 15 Q. Okay. Have you asked anybody 16 to find sources that disagree with you and to 17 try to find out why they disagree with you, 18 if they do? 19 MS. JOHNSTON: Object to the 20 form. 21 THE WITNESS: Well, as I shared 22 with you, I did have discussions with 23 both ACOG and SMFM, so I've asked them 24 for their -- where they are with the 25 documents. So I didn't hear anything</p>

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1 different than I already know.

2 QUESTIONS BY MR. TRACEY:

3 Q. Okay. Do you think that there

4 are qualified OB/GYNs and maternal-fetal

5 medicine experts in the world that may have a

6 different opinion than you?

7 A. Well --

8 MS. JOHNSTON: Object to the

9 form.

10 Go ahead.

11 THE WITNESS: -- certainly

12 we've already stated today that on the

13 Bauer report there is a -- Hugh Taylor

14 is an author who is an obstetrician,

15 gynecologist, a reproductive

16 endocrinologist, and he is an author

17 on that, but to my knowledge, he

18 doesn't see pregnant patients.

19 And I also found, I think,

20 among the 70 or so odd signatories in

21 that document, that there appear to be

22 two maternal-fetal medicine physicians

23 who signed on to the document --

24 QUESTIONS BY MR. TRACEY:

25 Q. You already told me all this

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1 there. I forgot.

2 MS. JOHNSTON: Did you --

3 QUESTIONS BY MR. TRACEY:

4 Q. I apologize. I already asked

5 this question.

6 MS. JOHNSTON: Did you

7 complete your response, Dr. D'Alton?

8 THE WITNESS: I was trying to

9 complete my response.

10 QUESTIONS BY MR. TRACEY:

11 Q. You don't need to answer it

12 again. You've already answered it. I

13 forgot. I withdraw the question. I quit. I

14 punt. However I can make it end.

15 MS. JOHNSTON: Okay.

16 QUESTIONS BY MR. TRACEY:

17 Q. Okay. When do you expect to

18 bill the lawyers for Johnson & Johnson?

19 MS. JOHNSTON: Object to the

20 form.

21 THE WITNESS: I haven't even

22 thought about that, but certainly in

23 the next month or so. I really don't

24 know. I haven't given that any

25 thought. I've been so busy working

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1 and looking at all of this.

2 And with all of my other

3 responsibilities, I haven't thought

4 about when I would submit a bill, so I

5 don't want to commit when I will

6 submit a bill because of my upcoming

7 schedule over the next couple months.

8 QUESTIONS BY MR. TRACEY:

9 Q. You have 160 hours times 600,

10 that's \$105,000?

11 MS. JOHNSTON: Object to the

12 form.

13 THE WITNESS: Math was never my

14 strong suit, so I haven't calculated

15 it.

16 QUESTIONS BY MR. TRACEY:

17 Q. Did you communicate with ACOG

18 and the Society for Maternal-Fetal Medicine

19 in writing?

20 A. No, I did not.

21 Q. How did you communicate with

22 them?

23 A. I called them.

24 Q. Who did you call?

25 A. I called in. I called

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1 Chris Zahn, who is the executive director of

2 ACOG, and I also called Tony Sciscione, who

3 is the president of the Society for

4 Maternal-Fetal Medicine, and I called

5 Jeff Kuller, who is the head of the

6 publications committee for SMFM.

7 Q. Did you tell them that you had

8 been hired by lawyers for Johnson & Johnson?

9 A. I told them I was an expert in

10 a case of Tylenol.

11 Q. Did you tell them that you were

12 hired by lawyers for Johnson & Johnson?

13 MS. JOHNSTON: Object to the

14 form.

15 THE WITNESS: I don't recall

16 that I did do that. I told them I was

17 an expert.

18 QUESTIONS BY MR. TRACEY:

19 Q. Why did you not disclose who

20 you were -- who you were hired by?

21 MS. JOHNSTON: Object to the

22 form. Misstates testimony.

23 And, Sean, I'll let you ask

24 another -- or let Dr. D'Alton finish

25 this, but we're at time.

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1 MR. TRACEY: Okay.

2 THE WITNESS: You know,

3 whether -- it may have come up that I

4 was an expert. I can't remember

5 that I specifically said that I was

6 retained by a -- by lawyers who were

7 representing Johnson & Johnson.

8 I did say that I was an expert,

9 and I would be giving testimony.

10 QUESTIONS BY MR. TRACEY:

11 Q. And why was that relevant to

12 your inquiry with them?

13 MS. JOHNSTON: Sean, we're

14 done.

15 QUESTIONS BY MR. TRACEY:

16 Q. Why was that relevant -- that

17 should have been produced. All of that

18 information.

19 Why was that relevant?

20 MS. JOHNSTON: Ex -- it's - I'm

21 sorry, what? Sean, you're out of

22 time. You can ask me the question, if

23 it's related to something specific

24 that you think should or should not

25 have been produced, but she's already

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1 told you that there are no documents

2 that are responsive. So I don't know

3 that she has anything else to tell you

4 on this.

5 We're also out of -- out of

6 time, and we are -- we've allowed you

7 to finish your last question, but I

8 think we're done.

9 QUESTIONS BY MR. TRACEY:

10 Q. Doctor, are there any other

11 communications you haven't told us about?

12 A. I've tried to be complete, you

13 know. I communicate with a lot of people. I

14 can't recall anything that would be

15 responsive right now, and certainly if I

16 think of anything, I shall let Sarah know.

17 But I tried to be responsive

18 to all of the materials that I had

19 considered.

20 Q. Do you recall talking --

21 MS. JOHNSTON: We're done.

22 QUESTIONS BY MR. TRACEY:

23 Q. -- or sending e-mails to

24 anybody?

25 MS. JOHNSTON: We're done.

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1 We're out of time, Sean. This is --

2 she's responded to all of your

3 questions, and she's already told you

4 there are no documents.

5 Yep. Let's go off the record.

6 MR. TRACEY: I'm actually not

7 sure that's what she said. That's why

8 I'm confused.

9 MS. JOHNSTON: Okay. Well, you

10 had seven hours.

11 MR. TRACEY: I can't hear.

12 What was that?

13 MS. RICHER: We said that

14 you're done asking questions. We're

15 going to take a two-minute break.

16 We'll come back and let you know if

17 we're going to ask any questions.

18 Thank you.

19 MR. TRACEY: Okay.

20 VIDEOGRAPHER: The time right

21 now is 6:25 p.m. We are off the

22 record.

23 (Off the record at 6:25 p.m.)

24 VIDEOGRAPHER: The time right

25 now is 6:28 p.m. We are back on the

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1 record.

2 MS. JOHNSTON: And, Sean, as I

3 said off the record, we have no

4 questions, so we are done, and thank

5 you.

6 MR. TRACEY: Oh, my God, we got

7 all dressed up and mic'ed up to do

8 that?

9 MS. JOHNSTON: I thought you

10 heard me off the record.

11 MR. TRACEY: No, no, I didn't

12 hear you. Sorry. Okay. All right.

13 Thanks, guys.

14 MS. JOHNSTON: Thank you.

15 VIDEOGRAPHER: The time right

16 now is 6:28 p.m. We are off the

17 record.

18 (Deposition concluded at 6:28 p.m.)

19 -----

20

21

22

23

24

25

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## ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

Mary E. D'Alton, MD \_\_\_\_\_ DATE \_\_\_\_\_

Subscribed and sworn to before me this \_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_.

My commission expires: \_\_\_\_\_

Notary Public

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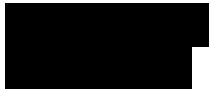
















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